

REDACTED DOCUMENTS RELATING TO DOCKET 7311

**EXHIBIT A – Filed redacted
Docket 7845 & 8118**

**EXHIBIT B – Filed redacted
Docket 7845**

**EXHIBIT C – No redactions – filed
unredacted**

EXHIBIT D – Filed redacted

EXHIBIT C

**SECOND SUPPLEMENTAL EXPERT REPORT
DAVID A. KESSLER, M.D.**

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APPENDICES

1. Materials Considered
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I. Qualifications

1. I received my M.D. degree from Harvard Medical School in 1979 and my J.D. degree from the University of Chicago Law School in 1978.

2. I did my pediatrics training at John Hopkins Hospital.

3. I was appointed in 1990 by President George H.W. Bush as Commissioner of the United States Food and Drug Administration and was confirmed by the United States Senate. I also served in that position under President William Jefferson Clinton until February 1997.

4. I have taught food and drug law at Columbia University Law School, and I have testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, I have published numerous articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. I have had special training in pharmacoepidemiology at Johns Hopkins Hospital.

5. As Commissioner, I had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act. I was responsible for overseeing five Centers within FDA. They included, among others, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. In addition to those duties, I placed high priority on getting promising therapies for serious and life-threatening diseases to patients as quickly as possible. During my tenure as Commissioner, the FDA announced a number of new programs, including: the regulation of the marketing and sale of tobacco products to children; nutrition labeling for food; user fees for drugs and biologics; preventive controls to improve food safety; measures to strengthen the nation's blood supply; and the MEDWatch program for reporting adverse events and product

problems involving both drugs and devices. I created an Office of Criminal Investigation within the Agency. I was directly involved with the regulation of medical devices. In addition, I established “The Committee for Clinical Review” that reviewed device evaluation and review. I worked closely with FDA’s Division of Drug Marketing, Advertising and Communications and was involved in establishing the Center for Devices and Radiological Health’s Promotion and Advertising Policy Staff.

6. I have a thorough knowledge and understanding of both routes for getting a medical device to the market – pre-market approval (PMA) and 510(k) clearance.

7. I am a senior advisor to TPG Capital, a leading global private equity firm, which owns pharmaceutical and biomedical companies. I served on the board of Aptalis Pharma, Tokai Pharmaceuticals, STOKe Therapeutics, and currently serve on the board of the medical device and biologics company Immucor, Inc. In these advisory and fiduciary capacities, I have advised companies on the standards and duties of care within the pharmaceutical and medical device industry. I also chaired the compliance committee of Aptalis, and I chair the quality committee of Immucor, which involves ensuring compliance with FDA laws and requirements.

8. In this report I use the term “Bard” to mean any of the following entities: Impra, Nitinol Medical Technologies (“NMT”), C.R. Bard, Inc., or Bard Peripheral Vascular.

9. I incorporate herein my Opening Report dated September 26, 2016, Supplemental Report dated March 3, 2017, and deposition testimony taken on October 5, 2016.

10. I was asked in this supplemental report to address:

- a. Medical device regulatory framework
- b. The 510(k) clearance process for Bard’s IVC filters
- c. Special controls assigned to IVC filters.

II. Medical Device Regulatory Framework

11. There are two routes to the market for a medical device. One route, the pre-market approval application (PMA) requires a full set of pre-clinical and clinical studies, is extensively reviewed by the FDA¹ and is generally viewed as the most thorough device application process.

12. PMA is the most detailed type of device marketing application and review required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). “The valid scientific evidence used to determine the effectiveness of a device shall

¹ There are numerous methodologies to assess FDA “review time”. FDA under MDUFA reports time to decision (“time to decision”). Another method is measuring from time of submission to time of clearance/approval (“time to clearance/approval”). Public reports indicate that it took on average 17.6 months for a first time pre-market approval (PMA) in 2014 and 32.2 months in 2013 (time to approval). Marie Thibault, *MDDI, FDA Approving Devices Faster*. March 26, 2015, FDA device approvals get faster still, dated 01/27/16

<http://www.epvantage.com/Universal/View.aspx?type=Story&id=554321&isEPVantage=yes>. Further public reports indicate that the average time for 510(k) clearance in 2006 was 97 days, in 2010 146 days, 2011 was 138 days. RAPS, Report on Average 510(k) Review Time of 138 Days Remains Close to Record Highs. <http://www.raps.org/focus-online/news/news-article-view/article/2884/>. For 2012 it was 168 days, in 2013 170 days, in 2014 178 days, in 2015 172 days, and in 2016 177 days. Emergo, *How Long it Takes the USFDA to Clear Medical Devices Via the 510(k) Process*, <https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf>. Further Emergo data indicates that Class II devices take an average 3-6 months and Class III devices take 18-30 months. *The FDA Medical Device Regulatory Process Timeline*, <https://its.utmb.edu/documents/FDA-Medical-Device-Regulatory-Process-Timeline.pdf>.

Bard submitted its 510(k) for Recovery (permanent) on July 11, 2002 and it cleared on November 27, 2002 (139 days from submission to clearance). The Recovery filter (retrievable) was submitted on April 28, 2003 and cleared on July 25, 2003 (88 days from submission to clearance). Bard submitted its G2 (permanent) 510(k) application on March 3, 2005 and it cleared on August 29, 2005 (179 days from submission to clearance). Bard submitted its G2 (retrievable) 510(k) application for G2 Recovery on November 1, 2007 and it cleared on January 15, 2008 (75 days from submission to clearance). Bard’s times from submission to clearance for its IVC filter appears consistent with average time to clearance for 510(k) devices.

consist principally of well-controlled investigations,” as defined in 21 CFR 860.7(f), and 21 CFR 860.7(e).

13. Devices that receive pre-market approval via a PMA application are said to be FDA “approved”.

14. The second route allows devices that are substantially equivalent to a marketed device (“the predicate”) to submit a 510(k) application that establishes “substantial equivalence.”

15. A device found by the FDA to be substantially equivalent to a predicate device is said to be “cleared” by FDA.

16. According to FDA:

“A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate.

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate; **or**
- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA:
 - does not raise new questions of safety and effectiveness; **and**
 - demonstrates that the device is at least as safe and effective as the legally marketed device.

A claim of substantial equivalence does not mean the new and predicate devices should be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.”²

²<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (Emphasis in original)

17. In my opinion, a 510(k) application must demonstrate that the device is substantially equivalent to a device that (1) was legally in commercial distribution in the US before May 28, 1976; or (2) has been determined by FDA to be substantially equivalent. 510(k) premarket applications can “piggyback” by demonstrating substantial equivalence to a device that has been found substantially equivalent. This practice has led to significant controversy and concern that many important devices are not being reviewed for safety and effectiveness.³

18. In my opinion, FDA’s 510(k) clearance process determines if the device is substantially equivalent to a predicate device already marketed. A determination by the FDA in the 510(k) process that a device is substantially equivalent to a predicate device is not a finding that the device is safe and effective for its intended conditions of use; it is a determination that the device is as safe and effective as the predicate device based on the information submitted by the manufacturer.

19. The purpose and effect of the 510(k) clearance process is to determine whether the new device has the same intended use and technological characteristics as the predicate device – i.e. the process focuses on equivalence rather than safety and efficacy.

20. There are instances where FDA can under the 510(k) clearance process request “clinical data.” FDA can request clinical data from a manufacturer to determine whether a device’s indication for use falls within the device’s intended use. FDA can also request clinical data if the agency has determined that the 510(k) submission has new technological characteristics relative to its predicate.

21. As stated by the Agency, clinical data is requested in the 510(k) process when there is an “important difference with the predicate device, e.g., new indications for the use or

³Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years (2011).

new technology.”⁴ The clinical data that is requested in the 510(k) process is aimed at answering the question of whether the device is substantially equivalent to the predicate. Such clinical data does not serve as an independent determination of the safety and effectiveness of the device. As stated in 21 C.F.R. 807.87(l) “Information required in a premarket notification submission”:

“Any additional information regarding the device requested by FDA that is necessary for the FDA to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the FDA to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.”

The FDA has stated in a Guidance document, “[t]he 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate) device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review. The standard for a determination of substantial equivalence in a 510(k) review is set out in section 513(i) of the FD&C Act. . . .”⁵

⁴ OIVD Premarket Notification (510(k)), April 22, 2003, Marjorie Shulman, Premarket Notification Staff, Office of Device Evaluation, CDER. www.european-food-safety.com/powerpoints/.../042203-Shulman.ppt

⁵ The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] — Guidance for Industry and Food and Drug Administration Staff (July 28, 2014) at 6.

III. 510(k) Clearance of Bard's IVC Filters

22. All of Bard's IVC filters were cleared to market via the 510(k) process and marketed as permanent devices with optional retrieval, including the Recovery (2002; 2003)⁶, G2 (2005; 2008)⁷, G2 Express and G2X Express (2008)⁸, Eclipse (2010)⁹, Meridian (2011)¹⁰, and Denali (2013)¹¹ Filters.

23. None of the predicates for any of Bard's optionally retrievable IVC filters, or the predicates for those predicates, ever received FDA approval via the PMA process¹².

Furthermore, the original pre-Amendment predicates were never assessed for safety and effectiveness. New substantially equivalent devices have not been shown to be safe and effective when comparison is made to pre-Amendment predicate devices that have not themselves been proven to be safe and effective.

24. Bard's permanent Recovery filter (K022236) and optionally retrievable Recovery filter (K031328) relied on IMPRA's Simon Nitinol Filter/Straight Line System (K970099) and Boston Scientific's Titanium Greenfield Filter (K901659) for its predicates. Bard's 510(k) submission for the G2 retrievability indication (K073090) relied on Bard's permanent G2 filter submissions (K052578) and (K062887) for its predicate. Bard's G2 Express snare filter (K080668) relied on Bard's retrievable G2 filter (K073090) for its predicate. Bard's G2 Express (G2X) filter relied on Bard's G2 Express snare filter (K080668) for its predicate. Bard's Eclipse (K093659) filter relied on Bard's G2 Express snare filter (K082305) for its predicate. Bard's

⁶ November 27, 2002 (permanent); 7/25/2003 (optional retrieval).

⁷ August 29, 2005 (permanent); 1/15/2008 (optional retrieval)

⁸ July 30, 2008

⁹ January 14, 2010

¹⁰ August 24, 2011

¹¹ May 15, 2013

¹² See, Schedule 3 of opening report signed September 26, 2016.

Meridian filter (K102511) relied on Bard's Eclipse filter (K101431) for its predicate, and Bard's Denali filter (K130366) relied on Bard's Eclipse filter (K101431) for its predicate.

25. Bard submitted clinical data for the initial 510(k) application for the Recovery filter (K022236), the 510(k) application for the G2 retrievability indication (K073090), and the Denali 510(k) application (K130366), although the Denali study was not complete at the time of the application's submission).¹³ Those clinical data did not, in my opinion, rise to the level of an independent demonstration of safety and effectiveness for any of Bard's IVC filters. Nothing about these submissions elevated the FDA review of Bard's IVC filters beyond a 510(k) review for substantial equivalence.

26. In my opinion, Bard did not submit any well-controlled completed studies to the FDA to support the agency's 510(k) clearance decisions. The clinical data submitted by Bard at the time of their 510(k) applications did not provide a basis by which the FDA could make a determination whether there is reasonable assurance that these optionally retrievable IVC filters were effective. The Asch Study, Everest, and Denali Trial¹⁴ were not well-controlled studies as defined by 21 C.F.R. 860.7 because they lacked any proper control group for comparison.¹⁵ In addition, none of Bard's clinical studies met the 2-year clinical follow up for adverse events including migration, filter fracture, filter tilting, filter fracture embolization, perforation, IVC

¹³ Bard did not submit clinical data specifically for the G2 permanent filter (K050558), G2 Express (K080668), G2X/Express (K082305), Eclipse (K093659), (K101431), and Meridian (K102511).

¹⁴ The Denali trial was not complete at the time Bard received clearance for its Denali filter and thus did not serve as a basis for the agency's clearance of the device. The final study report for the Denali filter is dated November 1, 2015.

¹⁵ BPV-17-01-00057953-8037; BPV-17-01-00052582-588; Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter, Asch, MD; Radiology: 835-44; December 2002; 5/2/16 Asch Deposition, 19:23 – 20:17 and 44:5-13; BPVE-502d-00000013-103; BPVEFILTER-01-01573378-469.

occlusion/thrombosis, worsening or new onset deep vein thrombosis and pulmonary embolism as set out by the agency in its February 28, 2013 letters regarding PRESERVE.¹⁶

27. On May 6, 2010, FDA issued a safety alert to IVC manufacturers including Bard that it would require collection of additional clinical data for currently marketed IVC filters. The alert stated: “The studies will address safety questions that remain unanswered for both permanent and retrievable filters.” The industry decided to undertake a study titled “PREDicting the Safety and Effectiveness of InferioR VEna Cava Filters” (PRESERVE). In my opinion, the fact that the FDA had unanswered questions about safety and efficacy more than decade after Bard introduced the Recovery filter supports the conclusion that the safety and efficacy of Bard’s IVC filters was never established.

28. The clinical data that Bard submitted as part of its 510(k) applications were provided to show that the new devices which had new features (including retrievability) did not raise any new safety or efficacy questions compared to the predicate device - - an essential requirement to support a finding of substantial equivalence under the 510(k) process. One of the reasons why the 510(k) substantial equivalence process is not a determination of safety and effectiveness is, as noted above, that the original predicate that was on the market prior to the 1976 MDA, was never itself shown to be safe and effective. Thus, the 510(k) substantial equivalence process is, in essence, a process of showing that the new device is no different than a predicate, where the predicate itself has never been shown to be safe and effective. A further problem with the 510(k) process that cleared Bard’s IVC filters is that it is premised on a new

¹⁶ FDA letters: BPV-17-01-00171677 (SNF), BPV-17-01-00171675 (Recovery), BPV-17-01-00171671 (G2), BPV-17-01-00171673 (G2X), BPV-17-01-0017169 (Eclipse), BPV-17-01-00178911 (Intent to participate in PRESERVE with Denali)

device being no different than a predicate device, but that new device is promoted in the marketplace as having new advantages over the prior device.

29. It has been reported there are no randomized controlled trials performed for common indications such as recurrent VTE despite adequate anticoagulation or contraindication to anticoagulation with IVC filters.¹⁷

30. Furthermore, single arm studies are incapable of assessing the efficacy for the IVC filter because there is no control to alternative treatments. *Id.*

31. The FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999)(“1999 Guidance” or “Guidance Document”) ¹⁸ states that human clinical investigations could be necessary to establish that a modified filter design is equivalent to currently marketed filters. *Id.*, at 5. The “intent of the clinical study should be to demonstrate that the rates of complications for the investigational filter are comparable to the other marketed vena cava filters.” *Id.* Bard has never conducted such a study.

32. In my opinion, the steps taken by Bard in obtaining 510(k) clearance of its IVC filters are consistent with the requirements to determine substantial equivalence that is part of the 510(k) clearance process. Nothing was required beyond what was necessary to establish substantial equivalence under the 510(k) clearance process.

¹⁷ See Data Desert for Inferior Vena Cava Filters: Limited Evidence, Supervision, and Research; Bikdeli, MD, et al.; JAMA Cardiology: Volume 2, No. 1, pp. 3-4; January 2017.

¹⁸ It should be noted that this Guidance enacted first in 1997 (Draft) and then in 1999 (Final) was written at a time when only permanent filters were on the market, and specifically notes that it covers only permanent filters which were not optionally retrievable as those were the only filters marketed at that time.

IV. Special Controls for IVC Filters

33. Congress established three classes of devices based on the regulatory requirements needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I, class II, and class III.

- a. Class I devices present no unreasonable risk of illness or injury and are subject to regulation through “general controls.” 21 U.S.C. 360c(a)(1)(A).
- b. Class II devices are potentially more harmful and are subject to general controls, but FDA in addition has authority to require that such devices comply with other “special controls.” 21 U.S.C. 360c(a)(1)(B).
- c. Class III devices are those that support human health, are of substantial importance in preventing impairment of human health or which present “a potential unreasonable risk of illness or injury” and are subject to premarket approval. 21 U.S.C. 360c(a)(1)(C).

34. The Safe Medical Device Amendments of 1990 (SMDA) and their implementing regulations (FR 58400 December 10, 1992), issued under my direction while I was Commissioner, in relevant part, codified FDA’s existing practices on the 510(k) decision-making process.¹⁹

35. The SMDA also allowed the agency to not rely exclusively on performance standards but on “special controls” which were less administratively burdensome on the agency. See 21 U.S.C. 360(d). Prior to 1990, the MDA of 1976 required that agency promulgate regulations setting out performance standards for each Class II device. The agency was criticized prior to 1990 for failing to issue any performance standards²⁰

¹⁹ Robert Gatling, The Regulation of Medical Devices, May 2009, <https://www.fda.gov/downloads/ForPatients/About/UCM410200.pdf>

²⁰ David A. Kessler et al., The Federal Regulation of Medical Devices, 317 NEW ENG. J. MED. 357, 357 (1987)

36. The special controls assigned to IVC filter devices generally are codified at 21 CFR 870.3375 and include:

- a. FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999)(“1999 Guidance”).
- b. Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA (August 30, 2002).
- c. Use of International Standards Organization's ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing.

A. FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999)(“1999 Guidance” or “Guidance Document”)

37. In my opinion, the 1999 Guidance applies generally to all IVC filters, and does not contain anything directed specifically to Bard IVC Filters.

38. In my opinion, in the 1999 Guidance, the FDA did not set specific requirements or recommendations for:

- a. performance standards for any IVC filter, including Bard’s optionally retrievable permanent filters.
- b. patient registries for any IVC filter, including for Bard’s optionally retrievable permanent filters.
- c. tracking requirements for any IVC filter, including for Bard’s optionally retrievable permanent filters.
- d. design controls for any IVC filter, including for Bard’s optionally retrievable permanent filters.
- e. clinical or pre-clinical trial parameters or testing methods.

39. In my opinion, until May 2014²¹ FDA set no post-market surveillance requirements specific to Bard’s optionally retrievable permanent filters²².

²¹ Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication (May 6, 2014 Update).

40. The FDA proposed the following labeling be included in the Attachment to the Guidance Document:

a. “INDICATIONS FOR USE

The labeling should include the following text:

The [NAME OF THE DEVICE] is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- pulmonary thromboembolism when anticoagulants are contraindicated;
- failure of anticoagulant therapy in the thromboembolic diseases;
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.”²³

b. “CONTRAINDICATIONS

The labeling should include the following contraindication:

The FDA issued this safety communication to address safety questions that remained unanswered for both permanent and retrievable filters. This alert required the collection of additional clinical data for IVC filters currently marketed in the United States. Manufacturers were given two options for obtaining the data: a. participate in the PRESERVE (PREdicting the Safety and Effectiveness of InferioR VEna Cava Filters) study, an independent, national clinical study to examine the use of IVC filters in the prevention of pulmonary embolism; or b. conduct post-market surveillance (522 Studies). The FDA stated: “The data gathered from the PRESERVE study and the 522 studies will help the FDA, manufacturers and health care professionals assess the use and safety profile of these devices, understand evolving patterns of clinical use of IVC filters and ultimately improve patients care.” This safety communication expresses the FDA’s position that as of 2014 the safety and effectiveness of IVC filters was still being investigated.

²² Starting February 28, 2013, FDA issued 522 Orders related to other manufacturers with regard to post-market surveillance. [<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm?sb=pdnd&s=t>].

²³ It should be noted that the Guidance document states “Manufacturers who wish to pursue other indications should contact FDA to determine the data necessary to support a new indication and the appropriate regulatory pathway.” Thus the Guidance document does not appear to support new or off label indications.

Vena Cava filters should not be implanted in patients with risk of septic embolism.

Your labeling may include other contraindications which are specific to your particular device design.”

c. “WARNINGS

The labeling should include information regarding the use of the device in patients undergoing magnetic resonance imaging (MRI). The following terminology should be used:

<u>MRI-SAFE:</u>	No additional risk to patients, but may affect the quality of the diagnostic information.
<u>MRI-Compatible:</u>	MRI-Safe and neither interferes with nor is affected by the operations of a MRI device.
<u>Non-Compatible:</u>	Neither MRI-Safe nor MRI-Compatible and should not be used in conjunction with MRI systems.”

41. In my opinion, the 1999 Guidance did not provide specific labeling language for any particular device addressing:

- a. Fracture
- b. Migration
- c. Perforation
- d. Tilt
- e. Inability to retrieve or embedding
- f. IVC filter thrombosis or occlusion of the IVC

42. In my opinion, the 1999 Guidance left open, and did not contain specific requirements or recommendations for, the following key issues that could reflect on the devices’ safety and effectiveness:

- a. Human clinical studies based on well-controlled scientific standards

- b. Sufficient long-term clinical testing to assure a device's safety and effectiveness.
- c. Sufficiently large human clinical studies to establish the safety and effectiveness of the device.

43. In my opinion, in the 1999 Guidance the specific nature of pre-clinical and clinical testing was not set out for any IVC filter, and particularly does not set specific performance standards for Bard's optionally retrievable permanent filters.

44. In my opinion, Bard's 510(k) applications did not contain certain data that could reflect on its devices' safety and effectiveness, such as:

- a. Human clinical studies based on well-controlled scientific standards
- b. Sufficient long-term clinical testing to assure a device's safety and effectiveness.
- c. Sufficiently large human clinical studies to establish the safety of the devices.²⁴

45. As noted in my opening report, Bard set its own performance standards for migration resistance and hook strength.²⁵ As noted in that report, in my opinion, those performance standards were flawed and set based on inaccurate data. As noted above, FDA did not set requirements, for example, for migration resistance or hook strength performance standards. Thus in my opinion the special controls were not specific to Bard's IVC Filters. In my opinion special controls for IVC filters did not assure either

²⁴ 510(k) applications: BPVE-01-00065938 (K970099); BPV-17-01-00057953(K022236); BPV-17-01-00054947 (K031328); BPV-FULLER-00006046 (K050558); BPV-17-01-000131271 (K052578); BPV-17-01-00125963 (K062887); BPV-17-01-00123629 (K073090); BPV-17-01-00130268 (K080668); BPV-17-01-00131320 (K082305); BPVEFILTER-02-00042265 (K093659); BPV-17-01-00171679 (K101431); BPV-17-01-00150192 (K102511); BPV-17-01-00147141 (K112497); BPV-17-01-00213103, BPV-17-01-00213189, BPV-17-01-00213689, BPV-17-01-00214188, BPV-17-01-00214588, BPV-17-01-00215018, BPV-17-01-00215974, BPV-17-01-00216074, BPV-17-01-00216174, BPV-17-01-00216474, BPV-17-01-00216874, BPV-17-01-00217098 (K130366), and BPV-17-01-00217322 (K143208).

²⁵ See pages 48-49; 135; 215; 219 of my opening report.

1) that Bard IVC filters did not raise new questions about safety and effectiveness, the key question in determining substantial equivalence, or 2) that the devices were safe and effective.

B. Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA (August 30, 2002)(“Sterility Guidance”)

46. The Sterility Guidance applies to all medical devices, makes no reference to any specific medical device, and establishes no performance standards specific to IVC filters (including any of Bard’s IVC Filters).

C. International Standards Organization's ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing

47. The ISO 10993 applies generally to all implantable medical devices and does not describe or establish requirements for safety or effectiveness for any particular medical device including any IVC filters, and specifically does not describe or establish requirements for safety and effectiveness for any of Bard’s IVC filters.

V. Conclusions²⁶

In my opinion:

48. A 510(k) application must demonstrate that the device is substantially equivalent to a device that (1) was legally in commercial distribution in the US before May 28, 1976; or (2) has been determined by FDA to be substantially equivalent. 510(k) premarket applications can “piggyback” by demonstrating substantial equivalence to a device that has been found substantially equivalent. This practice has led to significant controversy and concern that many important devices are not being reviewed for safety and effectiveness.

²⁶ See full report for my opinions.

49. FDA's 510(k) clearance process determines if the device is substantially equivalent to a predicate device already marketed. A determination by the FDA in the 510(k) process that a device is substantially equivalent to a predicate device is not a finding that the device is safe and effective for its intended conditions of use; it is a determination that the device is as safe and effective as the predicate device based on the information submitted by the manufacturer.

50. Bard submitted clinical data for the initial 510(k) application for the Recovery filter (K022236), the 510(k) application for the G2 retrievability indication (K073090), and the Denali 510(k) application (K130366), although the Denali study was not complete at the time of the application's submission). Those clinical data did not, in my opinion, rise to the level of an independent demonstration of safety and effectiveness for any of Bard's IVC filters. Nothing about these submissions elevated the FDA review of Bard's IVC filters beyond a 510(k) review for substantial equivalence.

51. Bard did not submit any well-controlled completed studies to the FDA to support the agency's 510(k) clearance decision. The clinical data submitted by Bard at the time of their 510(k) applications did not provide a basis by which the FDA could make a determination whether there is reasonable assurance that these optionally retrievable IVC filters were effective. The Asch Study, Everest, and Denali Trial were not well-controlled studies as defined by 21 C.F.R. 860.7 because they lacked any proper control group for comparison. In addition, none of Bard's clinical studies met the 2-year clinical follow up for adverse events including migration, filter fracture, filter tilting, filter fracture embolization, perforation, IVC occlusion/thrombosis, worsening or new onset deep vein thrombosis and pulmonary embolism as set out by the agency in its February 28, 2013 letters regarding PRESERVE.

52. On May 6, 2010, FDA issued a safety alert to IVC manufacturers including Bard that it would require collection of additional clinical data for currently marketed IVC filters. The alert stated: “The studies will address safety questions that remain unanswered for both permanent and retrievable filters.” The industry decided to undertake a study titled “PREdicting the Safety and Effectiveness of InferioR Vena Cava Filters” (PRESERVE). In my opinion, the fact that the FDA had unanswered questions about safety and efficacy more than decade after Bard introduced the Recovery filter supports the conclusion that the safety and efficacy of Bard’s IVC filters was never established.

53. The steps taken by Bard in obtaining 510(k) clearance of its IVC filters are consistent with the requirements to determine substantial equivalence that is part of the 510(k) clearance process. Nothing was required beyond what was necessary to establish substantial equivalence under the 510(k) clearance process.

54. The 1999 Guidance applies generally to all IVC filters, and does not contain anything directed specifically to Bard IVC Filters.

55. In the 1999 Guidance, the FDA did not set specific requirements or recommendations for: performance standards for any IVC filter, including Bard’s optionally retrievable permanent filters, patient registries for any IVC filter, including for Bard’s optionally retrievable permanent filters, tracking requirements for any IVC filter, including for Bard’s optionally retrievable permanent filters, design controls for any IVC filter, including for Bard’s optionally retrievable permanent filters, clinical or pre-clinical trial parameters or testing methods.

56. Until May 2014, FDA set no post-market surveillance requirements specific to Bard’s optionally retrievable permanent filters.

57. The 1999 Guidance did not provide specific labeling language for any particular device addressing: fracture, migration, perforation, tilt, inability to retrieve or embedding, IVC filter thrombosis or occlusion of the IVC

58. The 1999 Guidance left open, and did not contain specific requirements or recommendations for, the following key issues that could reflect on the devices' safety and effectiveness: human clinical studies based on well-controlled scientific standards, sufficient long-term clinical testing to assure a device's safety and effectiveness, sufficiently large human clinical studies to establish the safety and effectiveness of the device.

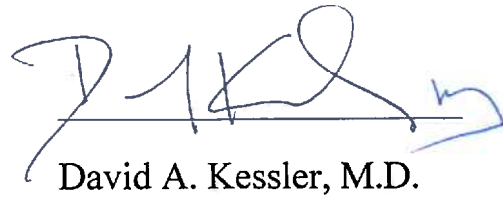
59. In the 1999 Guidance the specific nature of pre-clinical and clinical testing was not set out for any IVC filter, and particularly does not set specific performance standards for Bard's optionally retrievable permanent filters.

60. Bard's 510(k) applications did not contain certain data that could reflect on its devices' safety and effectiveness, such as: human clinical studies based on well-controlled scientific standards, sufficient long-term clinical testing to assure a device's safety and effectiveness, sufficiently large human clinical studies to establish the safety of the devices.

61. As noted in my opening report, Bard set its own performance standards for migration resistance and hook strength. As noted in that report, in my opinion, those performance standards were flawed and set based on inaccurate data. As noted above, FDA did not set requirements, for example, for migration resistance or hook strength performance standards. Thus in my opinion, the special controls were not specific to Bard's IVC Filters. In my opinion special controls for IVC filters did not assure either 1) that Bard IVC filters did not raise new questions about safety and effectiveness, the key question in determining substantial equivalence, or 2) that the devices were safe and effective.

July 15, 2017

Date

DAK 
David A. Kessler, M.D.

DOCUMENTS CONSIDERED FOR SECOND SUPPLEMENTAL REPORT

All materials referenced and or discussed within this Second Supplemental Expert Report are incorporated herein.

My Opening Report dated September 26, 2016, along with all materials referenced, discussed, cited, considered and/or relied upon therein, as well as all appendices and schedules to the same

My Supplemental Report dated March 3, 2017, along with all materials referenced, discussed, considered and/or relied upon therein, as well as all appendices and schedules to the same

All relevant statutes, regulations and guidances.

All depositions taken in this litigation and exhibits to the same.

All citations in all expert reports in this litigation.

All FDA clearance letters for all of Bard's optionally retrievable IVC filters.

All 510(k) applications for all of Bard's optionally retrievable IVC filters.

All exhibits to Bard's Motion for Summary Judgment filed March 24, 2017

Marie Thibault, *MDDI, FDA Approving Devices Faster*. March 26, 2015, FDA device approvals get faster still, dated 01/27/16

<http://www.epvantage.com/Universal/View.aspx?type=Story&id=554321&isEPVantage=yes>

Emergo, *How Long it Takes the USFDA to Clear Medical Devices Via the 510(k) Process*, <https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf>

The FDA Medical Device Regulatory Process Timeline, <https://its.utmb.edu/documents/FDA-Medical-Device-Regulatory-Process-Timeline.pdf>

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>

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<https://www.fda.gov/downloads/ForPatients/About/UCM410200.pdf>

David A. Kessler et al., The Federal Regulation of Medical Devices, 317 NEW
ENG. J. MED. 357, 357 (1987)

Data Desert for Inferior Vena Cava Filters: Limited Evidence, Supervision, and
Research; Bikdeli, MD, et al.; JAMA Cardiology: Volume 2, No. 1, pp. 3-4;
January 2017

Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35
Years (2011)

OIVD Premarket Notification (510(k)), April 22, 2003, Marjorie Shulman,
Premarket Notification Staff, Office of Device Evaluation, CDER.
www.european-food-safety.com/powerpoints/.../042203-Shulman.ppt

The 510(k) Program: Evaluating Substantial Equivalence in Premarket
Notifications [510(k)] —Guidance for Industry and Food and Drug Administration
Staff (July 28, 2014)

FDA Guidance for IVC Filter 510(k) Submissions (November 26, 1999) BPV17-
01-00034593-604

International Standards Organization's ISO 10993 Biological Evaluation of
Medical Devices Part I: Evaluation and Testing

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA
(August 30, 2002)(“Sterility Guidance”) BPV-17-01-00001961 – BPV-17-01-
00001968

Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter,
Asch, MD; Radiology: 835-44; December 2002;

May 2, 2016 Deposition of Murray Asch

June 6, 2017 Deposition of Robert Carr

BPVE-502d-00000013-103

BPV-17-01-00057953-8037

BPV-17-01-00052582-588

BPVEFILTER-01-01573378-469

BPV-17-01-00171677

BPV-17-01-00171675

BPV-17-01-00171671

BPV-17-01-00171673

BPV-17-01-0017169

BPV-17-01-00178911

510(k) applications: BPVE-01-00065938 (K970099); BPV-17-01-00057953(K022236); BPV-17-01-00054947 (K031328); BPV-FULLER-00006046 (K050558); BPV-17-01-000131271 (K052578); BPV-17-01-00125963 (K062887); BPV-17-01-00123629 (K073090); BPV-17-01-00130268 (K080668); BPV-17-01-00131320 (K082305); BPVEFILTER-02-00042265 (K093659); BPV-17-01-00171679 (K101431); BPV-17-01-00150192 (K102511); BPV-17-01-00147141 (K112497); BPV-17-01-00213103, BPV-17-01-00213189, BPV-17-01-00213689, BPV-17-01-00214188, BPV-17-01-00214588, BPV-17-01-00215018, BPV-17-01-00215974, BPV-17-01-00216074, BPV-17-01-00216174, BPV-17-01-00216474, BPV-17-01-00216874, BPV-17-01-00217098 (K130366), and BPV-17-01-00217322 (K143208)

21 U.S.C. 360c(a)(1)(A)

21 U.S.C. 360c(a)(1)(B).

21 U.S.C. 360c(a)(1)(C)(ii)(II)

21 U.S.C. 360(d)

21 C.F.R. 807.87(l)

21 C.F.R. 860

21 C.F.R. 860.7

21 C.F.R. 860.7(e)

21 C.F.R. 860.7(f)

21 C.F.R. 870.3375

FR 58400 December 10, 1992

APPENDIX 2

PRIOR TESTIMONY

PRIOR TESTIMONY AND STATEMENT OF COMPENSATION

Dr. David Kessler testified at trial or deposition in the following cases over the last seven years:

- *In re Risperdal*, Philadelphia, PA and Texas cases, including No. 2012CCV-61916-1 (Tex. Dist. Ct. filed Oct. 2, 2012 and Pledger and Walker)
- *Wells v. Allergan, Inc.* No. 12-973 (W.D. Okla. filed Sept. 4, 2012); *Drake v. Allergan*, Case No. 2013 vv00234 (U.S. Dist. Ct. Burlington, Vermont)
- *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187 (S.D.W.V. filed July 15, 2010)
- *SB v. Ortho-McNeil-Janssen Pharm., Inc. (In re Risperdal Litig.)*, No. 100503629 (Pa. Ct. Com. Pl. filed May 27, 2010)
- *In re Yaz & Yasmin (Drospirenone) Marketing, Sales Practices & Prods. Lib. Litig.*, MDL No. 2100 (J.P.M.L. filed July 30, 2009)
- *In re Flonase Antitrust Litigation* (American Sales Company, Inc. v. Smithkline Beecham Corp.), 08-cv-3149, United States District Court, Eastern District of Pennsylvania
- *Pharmathene, Inc. v. Siga Techs., Inc.*, No. 2627 (Del. Ch. filed Dec. 20, 2006)
- *Commonwealth v. Merck & Co.*, No. 09-1671 (Ky. Cir. Ct. filed Sept. 28, 2009) (and Utah)
- *State v. Merck & Co.*, No. 05-3700 (E.D. La. filed Aug. 5, 2005)
- *Commonwealth Care Alliance v. AstraZeneca Pharm. L.P.*, No. SUCV2005-269 (Mass. Super. Ct. filed Jan. 25, 2005)
- *Smith & Nephew, Inc. v. N.H. Ins. Co.*, No. 04-3027 (W.D. Tenn. filed Dec. 17, 2004)
- *In re Neurontin Marketing, Sales Practices & Prods. Liab. Litig.*, MDL No. 1629 (D. Mass. filed June 9, 2004)
- *Brown v. Am. Brands, Inc.*, No. 711400 (Cal Super. Ct. filed June 10, 1997)
- *In re: Actos (Pioglitazone) Prods. Lib. Litig.*, No. 11-md-2299 (W. D. La. filed Dec. 29, 2011)
- *Brown v RJ Reynolds Tobacco Company et al.*, No. 2007 CA 002855 (Fla. Cir. Ct. filed Nov. 28, 2007)
- *In re Merck & Co., Inc. Sec., Deriv. & "ERISA" Litig.*, MDL No. 1658, No. 05-2367 (D.N.J. filed May 5, 2005)
- *In re Prograf Antitrust Litigation* MDL2242, United States District Court of Massachusetts
- *In re Nexium Antitrust Litigation* MDL 2419 United States District Court, District of Massachusetts
- *Cabana v. Stryker*. Superior Court of State of California, Los Angeles
- *In Re: Fosamax Litigation*, Civil Action No. 282, (Superior Court of New Jersey, Atlantic County) and Case No. 30-2012-00547764 (Superior Court of California, Orange County)
- *Western Sugar Coop et al v. Archer-Daniels-Midland Co, et al*, U.S. District Court, Central District of California, No. 11-03473
- *H.B., et al. v. Abbott Laboratories*, No. #15-cv-702-NJR-SCW (U.S District Court, Southern District of Illinois filed June 26, 2015)
- *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419 (United States District Court of Massachusetts filed 2/14/13)
- *In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, MDL No. 3:11-md-02244 (N.D. Tex. filed May 24, 2011)
- *In re: Tropicana Orange Juice Mktg. & Sales Practices Litig.*, MDL No. 2353, No. 2:11-cv-07382 (D.N.J. filed Aug. 10, 2012)
- *In re Cipro Cases I and II*, Nos. 4154 & 4220 (Cal. Super. Ct., filed Feb. 25, 2002)
- *Anders v. Medtronic, Inc., et al.*, No. 1322-CC10219-02 (Mo Cir. Ct.)
- *Austin v. C.R. Bard, Inc., et al.*, Case No. 15-cv-8373 (Circuit Court of the 17th Judicial Circuit (Div. 7), Broward County, Florida).
- *In re: Zolofit Litigation*, JCCP No. 4771 (Superior Court of California, Orange County)
- *In re: Testosterone Replacement Therapy Product Liability Litigation*, MDL No. 2545 (U.S. District Court, Northern District of Illinois – Eastern Division)
- *In re: Xarelto Products Liability Litigation*, MDL No. 2592 (U.S. District Court, Eastern District of Louisiana – New Orleans Division)

- ***In re: Benicar (Olmesartan) Product Liability Litigation***, Civil No. 15-2606 (U.S. District Court, District of New Jersey)
- ***In re: Cook Medical, Inc. IVC Filters Marketing, Sales Practices and Product Liability Litigation***, MDL No. 2570 (U.S. District Court, Southern District of Indiana – Indianapolis Division)
- ***State of Texas, ex rel. v. AstraZeneca LP, et al.***, Case No. D-1-GN-13-003530 (District Court of Travis County, Texas)

Dr. David Kessler provided sworn expert statements in the following cases over the last five years:

- ***DePuy ASR Hip System Cases***, No. CJC-10-4649 (Cal. Super. Ct. filed Dec. 22, 2010)
- ***Cordero v. Endoscopy Ctr. of S. Nev. LLC (In the Matter of Endoscopy Ctr. & Associated Businesses)***, No. 08-A-558091-C (Nev. Dist. Ct. filed Feb. 28, 2008)
- ***Jenkins et. al. v. Medtronic, Inc. et al.***, Case No. 2:13cv02985 (W.D. Tenn.)

Hourly rate: \$1000/hr

EXHIBIT D

SCHEDULES

DAVID A. KESSLER, M.D.

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Schedule 1 – Plaintiffs

Schedule 1 – Plaintiffs

Case Number	Plaintiff Name	Plaintiff Lead Attorney/Firm	Device Type	Injury
2:15-cv-01625-PHX-DGC	Milton, Gary	Martin Hammers Button		
2:15-cv-01627-PHX-DGC	Ocasio, Denise	Martin Johnson Arbon Julmiste Button		
2:15-cv-01628-PHX-DGC	Wyatt, Casey	Johnson Reed-Zaic Boatman Stoller		
2:15-cv-01629-PHX-DGC	Tillman, Lessie	Cannon Johnson Reed-Zaic Smith Heaviside Lopez Boatman Stoller		
2:15-cv-01634-PHX-DGC	Kruse, Carol	Schicker	G2	Device unable to be retrieved / Migration of the filter
2:15-cv-01638-PHX-DGC	Sizemore, David L.	Martin Arbon Armitage	G2	Fracture, perforation of filter strut(s) into organs
2:15-cv-01639-PHX-DGC	Miller, Albert	McCarley Smith		
2:15-cv-01641-PHX-DGC	Rowe, Joseph	Martin Arbon Carpenter	Eclipse	Fracture, Device unable to be retrieved
2:15-cv-01644-PHX-DGC	Merritt, Dawn	Montroy Smith Heaviside Johnson		
2:15-cv-01646-PHX-DGC	Munson, Tonya	Martin Van Der Veer Freese Bossier Arbon	G2	Fracture, perforation of filter strut(s) into organs, a fractured strut extended into anterior portion of the L4 vertebrae
2:15-cv-01649-PHX-DGC	Jackson, Alice	Freiberg Martin Button	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved

		Arbon		
2:15-cv-01652-PHX-DGC	Henley, Angela M.	Martin Button Martin Arbon		
2:15-cv-01655-PHX-DGC	Roeder, Marcia	Zoll	Meridian	Fracture, perforation of filter strut(s) into organs
2:15-cv-01658-PHX-DGC	Branch, Debra	Martin Arbon	Recovery	Fracture, perforation of filter strut(s) into organs
2:15-cv-01659-PHX-DGC	Graham, Juanita C. <i>As legal representative for Coronado, Erica</i>	Martin	G2 Express	Tilt with filter embedded in wall of the IVC, the IVC filter was clotted
2:15-cv-01660-PHX-DGC	Conn, Charles	Martin		
2:15-cv-01663-PHX-DGC	Anderson, Mary Jo	Martin Arbon	Meridian	Fracture, a fractured strut remains embedded in the anterior wall of the vena cava
2:15-cv-01666-PHX-DGC	Ebert, Melissa	Martin Hickey Button Mankoff Katz		
2:15-cv-01667-PHX-DGC	Wetzel, Vicki	Katz		
2:15-cv-01668-PHX-DGC	Keen, Harry	Dalimonte Miller Katz Toriseva Ryan		
2:15-cv-01643-PHX-DGC	McClarty, Homer W.	Hilborn		
2:15-cv-01690-PHX-DGC	Hough, Brittany Ann	Krangle		
2:15-cv-01691-PHX-DGC	Cason, Pamela B.	Lopez Schneider Hammers		
2:15-cv-01707-PHX-DGC	Fox, Susan	Kendall Reed-Zaic Kirchmer Lemoine McKey Rudman		
2:15-cv-01708-	Pickard, Jason	Houssiere		

PHX-DGC		Kauffman		
2:15-cv-01623-PHX-DGC	Leus, George	Johnson Montee Cannon	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:15-cv-01710-PHX-DGC	Deserio-Mintz, Jessica	Alonso		
2:15-cv-01956-PHX-DGC	Williams, Tamika	Milling		
2:15-cv-01712-PHX-DGC	Coker, Jennifer R.	Grant Lopez		
2:15-cv-01714-PHX-DGC	Noterman, Pamela	Burke Chaikin	G2x	Fracture, Perforation of filter strut(s) into organs, migration of entire filter to heart, extrusion of the stent strut; structure in the right ventricle; IVC filter through right jugular vein
2:15-cv-01717-PHX-DGC	Blacketer, Heather	Campbell Corl	G2	Fractured, Perforation of filter struts into organs, tilt with filter embedded in wall of IVC, unable to be retrieved.
2:15-cv-01719-PHX-DGC	Cronan, Christopher Cronan, Jeanette - deceased	Kirakosian	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:15-cv-01720-PHX-DGC	Murray, Melonee	Lopez Pahlke Kelly		
2:15-cv-01721-PHX-DGC	Fregeau, Thomas	Kenefick	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:15-cv-01722-PHX-DGC	Scott, Sandra	Turner Johnson		
2:15-cv-01723-PHX-DGC	Green, Debra	Johnson	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:15-cv-01725-PHX-DGC	Castillo, Luis	Martin Boatman Stoller	G2 Express	Perforation of filter strut(s) into organs
2:15-cv-01726-PHX-DGC	Geter, Clifford	Van Der Veer Freese Bossier		
2:15-cv-01738-PHX-DGC	Castellano, Debra	Reed-Zaic Smith Heaviside		

		Johnson		
2:15-cv-01739-PHX-DGC	Parker, Jessica	Mendenhall Van Der Veer Freese	G2	Perforation of filter strut(s) into organs
2:15-cv-01741-PHX-DGC	Shackleford, David	Smith Heaviside Anderson		
2:15-cv-01742-PHX-DGC	Smith, Erin	Kirchmer		
2:15-cv-01878-PHX-DGC	Winland, Ernest	Rowland Dalimonte Toriseva		
2:15-cv-01879-PHX-DGC	Schweska, Linda	Dalimonte Rowland		
2:15-cv-01881-PHX-DGC	Epps, Donald	Dalimonte Wetherall Toriseva	Eclipse	Perforation of filter strut(s) into organs, device unable to be retrieved, migration of IVC filter to stomach
2:15-cv-01883-PHX-DGC	Peery, Robert	Dalimonte Boren		
2:15-cv-01884-PHX-DGC	Landress, Emily	Martin Hammers	Meridian	Fracture, perforation of filter strut(s) into organs
2:15-cv-01885-PHX-DGC	Noonan, John (Takada, Joji)	Plattenberger	G2 Express	Migration of entire filter to heart
2:15-cv-01886-PHX-DGC	Mercurio, Michelle	Matarazzo	G2 Express	Perforation of filter strut(s) into organs; tilt with filter embedded in wall of the IVC; device unable to be retrieved; multiple struts and retrieval hook have perforated through the IVC accord to radiology reports and vascular surgeon, Roan Glocker, M.D.'s note of 12/10/14 at Strong Memorial Hospital. He cites risks as thrombus or fistulization. However, at that point, he did not think prophylactic removal was appropriate. Patient is also on anticoagulation (Xarelto) for history of arterial thrombus, further complicating any bleeding event caused by further device migration.
2:15-cv-01899-	Mears, Claudette	Urban		

PHX-DGC	Y.	Dalimonte Toriseva		
2:15-cv-01900- PHX-DGC	Smullen, Lisa	Johnson Reed-Zaic		
2:15-cv-01915- PHX-DGC	Voight, Angela	Dalimonte Murphy Robison		
2:15-cv-01925- PHX-DGC	Morgan, Pharris	Martin		
2:15-cv-01926- PHX-DGC	O'Neill, Denise	Martin Lopez	G2	Fracture, filter migration between the aorta and spine; migration of fractured filter leg to right ventricle, migration of fractured filter leg to back, unable to remove fractured filter leg from back.
2:15-CV-02090- PHX-DGC	Edwards, Myra	Langdoc Baughman Hatten Budd Saucer	Meridian	Fracture, tilt with filter embedded in wall of the IVC, migration of filter
2:15-CV-02091- PHX-DGC	Rowden, Catherine	Quinn Driscoll Lopez	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:15-CV-02093- PHX-DGC	Duffie, Mary	Nations Smith Daniel		
2:15-CV-02096- PHX-DGC	Gross, Kevin	Branch Peppelman Funk	Unknown	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:15-CV-02139- PHX-DGC	Tate, Jennifer	Doebler	G2	Fracture, perforation of filter strut(s) into organs
2:15-CV02142- PHX-DGC	Owens, William	Lopez Zonies	Eclipse	Fracture, tilt with filter embedded in wall of the IVC, migration of fractured filter strut to right ventricle, unable to remove strut in heart (retained strut in right ventricle).
2:15-CV-02145- PHX-DGC	Middleton, Sheila	Freiberg	Eclipse	Fracture / Tilt with filter embedded in wall of the IVC Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered

				stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, anxiety and stress that the fractured strut will move while she is sleeping or performing her daily activities, such as walking, bathing, shopping for groceries and performing her household chores.
2:15-CV-02155-PHX-DGC	Becker, Dean	Aragon Carey Byszewski		
2:15-CV-02227-PHX-DGC	Rouse, Cheryl	Park	Denali	Fracture, Perforation of the filter strut(s), Device unable to be retrieved
2:15-CV02302-PHX-DGC	Brown, Karen	Stern Kramer Liebhard		
2:15-CV02303-PHX-DGC	Duckett, Norma	Davis		
2:15-CV02304-PHX-DGC	Callahan, Michael	Relkin Goldenberg	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:15-CV02308-PHX-DGC	Darwactor, Joanna	Whitley		
2:15-CV02379-PHX-DGC	Hillsburg, Tammy	Gallagher		
2:15-CV02380-PHX-DGC	Yates, Donald	Hovde Dalimonte		
2:15-CV02446-PHX-DGC	Lorthe, Christine	Johnson	Recovery	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:15-CV02462-PHX-DGC	Rodrigue, Debra	Kingsdorf Barrios Wool	G2 Express	Device unable to be retrieved, perforation of the struts into the vena cava
2:15-CV02463-PHX-DGC	Taylor, Kendrick	Woodson	Meridian	Fracture
2:15-CV02573-PHX-DGC	Eaker, Thomas	McSweeney	G2	Device unable to be retrieved
2:15-CV02635-PHX-DGC	Smith, Nannette	Dalimonte Toriseva		
2:15-CV02642-PHX-DGC	Keegan, Audrey	Kramer Conlin		Fracture / Migration from initial position

				Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering loss of enjoyment of life and other losses.
2:15-CV02647-PHX-DGC	Jones, Patricia	Milling		
2:15-CV02648-PHX-DGC	Beal, Tommy Lee	Conlin Grimes	G2X	Migration of entire filter to heart, tilt with filter embedded in wall fo the IVC, device unable to be removed, bleeding
2:15-CV02655-PHX-DGC	Shropshire, Jennifer	Herren Flaherty	G2	Back/abdominal pain, device propagating outside vena cava
2:15-CV02656-PHX-DGC	Piazza, Garry Leigh	Seltz Fleishman		
2:16-CV00002-PHX-DGC	Zybert, Freedom	Brenes	G2	Clinical depression, anxiety, unable to work, on going medical issues related to the remaining IVC Filter Fragments
2:16-CV00008-PHX-DGC	Harbridge, Robert	Freeman Weisbrod Boone		
2:16-CV00010-PHX-DGC	Caldwell, Alec	Bossier	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be removed, perforation of the IVC with multiple prongs outside the IVC and abutting the abdominal aorta. "Grossly tilted" filter
2:16-CV00025-PHX-DGC	Gill, Michael	Dalimonte Toriseva		
2:16-CV00027-PHX-DGC	Agnew, Lynn Ann	Lopez	Recovery	Fracture, Three legs perforating; one into the right renal vein, a second penetrating the Vena Cava directed towards the aorta, a third directed posteriorly causing chronic erosive change on the L3 vertebral body
2:16-CV00034-PHX-DGC	King, Linda	Migliori Thompson	Eclipse	Migration of the filter at the iliac bifurcation

		Duane		
2:16-CV00040-PHX-DGC	Kinney, Regina	Lopez	Recovery (2) filters same type	Fracture, Migration of entire filter to heart
2:16-CV00058-PHX-DGC	Bruhn, Cynthia	Lopez	Eclipse	Tilt with filter embedded in wall of the IVC
2:16-CV00059-PHX-DGC	Dolan, Marie	Lopez	G2	Device unable to be retrieved, perforation with at least one of the times seen outside of the vena cava, posterior to abdominal aorta, and at least one time extending inferiorly into the right gonadal vein.
2:16-CV00060-PHX-DGC	Batchelder, Phillip	Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, perforation of the filter tip completely outside the inferior vena cava, with erosion of the filter legs through the vacal wall and renal vein, superimposing the aorta, which made endovascular removal impossible and required open extraction of the filter
2:16-CV00061-PHX-DGC	Layman-Hanes, Michelle	Nolen	Eclipse	Perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00067-PHX-DGC	King, Michael	Cowper	Bard G2	Device unable to be retrieved / Pain and swelling in the legs, unable to bend over and put on socks, fear of fracture.
2:16-CV00079-PHX-DGC	Edwards, Wilford	Bond	Eclipse	Tilt with filter embedded in wall of the IVC
2:16-CV00090-PHX-DGC	Thomas, Karen	Goldstein	G2	Fracture, Perforation of filter strut(s) into organs, device unable to be retrieved, bleeding
2:16-CV00097-PHX-DGC	Anderson, Debbie	Lopez	Meridian	Fracture, migration of fractured strut to liver, unable to remove fractured strut
2:16-CV00109-PHX-DGC	Baldwin, Vivian	Lopez	Recovery	Fracture, migration of fractured strut to liver, unable

				to remove fractured strut
2:16-CV00110-PHX-DGC	Gill, Denise	Lopez		
2:16-CV00111-PHX-DGC	Linster, Anders	Lopez	Recovery	Fracture, migration of fractured strut to the heart and subsequent migration to the left lower parenchymal pleural region of the lung
2:16-CV00112-PHX-DGC	Peters, Paula	Lopez	G2	Tilt with filter strut(s) into organs, Perforation of one strut above segments right lateral wall of the abdominal aorta, two struts perforating just posterirot to the aorta at the same level, one of the struts extending just posterior to the duodenum, tip of the filter tilted abutting the IVC wall.
2:16-CV00113-PHX-DGC	Seaman, Mark	Lopez	G2	Fracture, Device unable to be retrieved, Fractured strut migrated to ventricular vein
2:16-CV00114-PHX-DGC	Wood, Maygret	Lopez	G2X	Fracture/ Strut migration to the right ventricle, development of Pericardial Effusion, Pleural Effusion, Bilateral PE, Required Pericardial Window and open retrieval of strut, Perforation if IVC/ Plaintiff refers Defendants to her medical records for complete details of her injuries suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, emotional and physical pain and suffering. Plaintiff developed severe chest pain about 1 month after implant and was finally admitted to the hospital on 11/7/2010, when it was discovered that she had an impressive pericardial

				<p>effusion; she underwent pericardiocentesis and thoracentesis of a left side pleural effusion, and was discharged after 8 days. However, she quickly returned to the ER with recurrent shortness of breath and gastric/substernal pain and a chest CT on 11/17/2010 showed moderate bilateral PE, as well as a metallic linear density projecting in the right ventricle, possibly perforating into the pericardium; upon further review, a similar abnormality was seen on abdomen CTs of 10/25/2010 and 11/5/2010, which showed only 11 struts remaining on the filter, which originally had 12. She underwent a pericardial window and open removal of the fractured strut on 11/17/2010, as it was now perforating the right ventricular free wall and straddling the pericardial space. At this time, it was also noted that one of the struts of the filter was penetrating the wall of the IVC, but the filter was not removed, given the potential risk involved. A repeat CT on 2/21/2013 confirmed that the filter remained in place, with the 11 struts intact, and it was decided that she would continue to monitor it, as removal was risky and not guaranteed. Client died of metastatic breast cancer on 5/9/2015, with the filter still implanted</p>
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2:16-CV00115-PHX-DGC	Waliczek, Brett	Lopez	G2	Tilt with thrombus extending above the level of the filter, filter pressing against the spine and puncturing the aorta; during open removal a vein had to be removed.
2:16-CV00121-PHX-DGC	Buracker, April	Cowper	Bard G2	Perforation of filter strut(s) into organs / Tilt with filter embedded in wall of the IVC / Filter leg became lodged in spine. Filter keg lodged in spine caused tremendous back pain. Irritable bowel caused by filter leg protruding into bowel. I was taken off the active kidney transplant list because of IVC filter.
2:16-CV00126-PHX-DGC	Barrow, Jamie	Dalimonte Toriseva	G2	Fracture, perforation of the filter strut(s) into organs
2:16-CV00129-PHX-DGC	Hesser-Schluter, Tammy	Branch Terry	Unknown	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00130-PHX-DGC	Ricker, Bradley	Lopez Carrie Capouellez	G2	Fracture, Rightward tilt, migration of fractured strut to the left pulmonary vein, retained filter and strut.
2:16-CV00137-PHX-DGC	Bures, Florence	Lopez Carrie Capouellez Michael Katz		
2:16-CV00138-PHX-DGC	Knotts, Roger	G&K Lopez	G2	Device unable to be retrieved Filter prevents me from getting medical treatment that I need, chest pains, anxiety
2:16-CV00140-PHX-DGC	Kuhn, John	G&K Lopez	Meridian	Irregular heartbeat, severe and persistent chest pains, shortness of breath, trouble maintaining healthy blood pressure, and anxiety
2:16-CV00143-PHX-DGC	Smith, Jodi	Dalimonte Toriseva	Recovery	Fracture
2:16-CV00148-PHX-DGC	Madson, Jay	Matthews Bossier	G2	Fracture, perforation of filter strut(s) into organs, migration

				abdominal aorta
2:16-CV00150-PHX-DGC	Borden, George Borden, Melody	Houssiere Kauffman	Eclipse	Tilt with filter embedded in wall of the IVC, perforation of filter prongs through the vena caval wall, resulting in development of a right-sided retroperitoneal hematoma following removal of the device and subsequent bilateral DVT as a result of extensive luminal manipulation from the filter removal and compression of the vena cava by the hematoma
2:16-CV00151-PHX-DGC	Torpey, Thomas	Dalimonte Toriseva	G2	Fracture, Device unable to be retrieved, Physicians have confirmed that at least one of the Plaintiff's IVC filter struts has fractured and migrated. They are unable to determine its current location or if it has perforated any organs
2:16-CV00153-PHX-DGC	Viola, Michael	Matthews Bossier	Recovery	Perforation of filter strut(s) into organs, Migration of entire filter to heart, Tilt with filter embedded in wall of the IVC
2:16-CV00154-PHX-DGC	Hardeman, Corrina	Matthews Bossier	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00160-PHX-DGC	Grygiel, Stephanie	McEwen	Eclipse	Fracture, perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00161-PHX-DGC	Gross, Nicole	Horne	Eclipse	Perforation of filter strut(s) into organs
2:16-CV00171-PHX-DGC	Nordin, Amber	Marlow	Eclipse	Tilt with filter embedded in wall of the IVC, Device unable to be retrieved; adhesions prevent removal.
2:16-CV00174-PHX-DGC	Anzaldua, Dezarae	DeGaris Setlz Fleishman	Denali	Tilt with filter embedded in wall of the IVC, device unable to be retrieved

2:16-CV00175-PHX-DGC	Kucharski, Deborah	DeGaris Seltz Fleishman	Eclipse	Fracture, device unable to be retrieved, filter tilted, fractured, leg migrated
2:16-CV00177-PHX-DGC	Bicica, Kirsten	Baron & Budd	G2	Fracture, device unable to be retrieved, perforation of IVC filter into aorta, DVTs and Pes
2:16-CV00178-PHX-DGC	Carter, Cheyenne	Baughman Budd	Denali	Device unable to be retrieved, suffered from DVTs and PE after filter was implanted.
2:16-CV00179-PHX-DGC	Curry, Kimberly	Baughman Budd	G2	Device unable to be retrieved, DVTs
2:16-CV00180-PHX-DGC	Dougal, Robert	Baughman Budd	G2	Perforation of the IVC
2:16-CV00181-PHX-DGC	Gibson, Judy	Baughman Budd	Meridian	Tilt with filter embedded in wall of the IVC, granulation of filter
2:16-CV00182-PHX-DGC	Hayes, Susan	Baughman Budd	Denali	Device unable to be retrieved
2:16-CV00183-PHX-DGC	King, Patty	Baughman Budd	Recovery	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, migration, calcification
2:16-CV00187-PHX-DGC	Radjewski, Farah E	Dalimonte Toriseva		
2:16-CV00188-PHX-DGC	Faulk, Mary L	Matthews Bossier	G2	Perforation of filter strut(s) into organs, migration of entire filter to the heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved, IVC filter migrated, flipped, rotated, and embedded
2:16-CV00190-PHX-DGC	Kaiser, Deborah A	Matthews Bossier	Recovery	Bleeding, Tilt
2:16-CV00191-PHX-DGC	Crowe, Lorene M	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, device unable to be retrieved, IVC filter migration
2:16-CV00193-PHX-DGC	Hudson, Ivana L	Matthews Bossier	G2	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved, migration, post implant DVT, arm of filter broke off, migrated to my lung and it is embedded there.

2:16-CV00194-PHX-DGC	White, Rhonda V	Matthews Bossier	Recovery	Fracture, Perforation of filter strut(s) into organs, Migration of entire filter to heart, One strut broke off and went into the heart.
2:16-CV00196-PHX-DGC	Salmon, Jered J	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, Device unable to be retrieved
2:16-CV00197-PHX-DGC	Webster, Russel J	Matthews Bossier	G2	Fracture, Migration of entire filter to heart, Tilt with filter embedded in wall of the IVC, Filter tilted and allowed a clot to pass through the lung and so a second filter had to be implanted.
2:16-CV00198-PHX-DGC	Barnett, Timothy A	Matthews Bossier	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be removed, embedment
2:16-CV00199-PHX-DGC	Harless, Terry J	Matthews Bossier	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, bleeding, migration into duodenum which caused a massive bleed, embedment
2:16-CV00200-PHX-DGC	Lieberman, Lenore B	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC
2:16-CV00201-PHX-DGC	Pikal, Bernard	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, Device unable to be retrieved, Tilt with filter embedded in wall of the IVC, Embedment
2:16-CV00202-PHX-DGC	Carlyle, James	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, migration of filter, filter hook from the iVC wall
2:16-CV00203-PHX-DGC	Presswood, Roger	Matthews Bossier	Recovery	Perforation of filter strut(s) into organs
2:16-CV00204-PHX-DGC	Perkins, Jason	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, one of the legs of the filter punctured my IVC

				wall causing pain
2:16-CV00205-PHX-DGC	Kouns, James	Matthews Bossier	G2	Perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved.
2:16-CV00-PHX-DGC	Richardson, Jacob	Lopez	G2	Tilt with filter embedded in wall of the IVC, severely malpositioned filter at a downward angulation, perforation of four struts out of the cava, retrieval cone appeared to have penetrated the cava and was now abutting the duodenum, open cavotomy
2:16-CV00208-PHX-DGC	Brassard, James	Goldenberg	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, penetration of vena cava posteriorly
2:16-CV00211-PHX-DGC	Jones, William T	Matthews Bossier	Denali	Device unable to be retrieved, it was placed to prevent blood clot, however, I still developed blood clots. Tilter filter, not able to be retrieved.
2:16-CV00212-PHX-DGC	Erlitz, Allen	G&K	Meridian	Additional blood clots, anxiety and mental distress
2:16-CV00213-PHX-DGC	Fairchild, Sherly	G&K	G2X	Severe and persistent pain in my right foot, overall weakness of my right leg, frequent numbness of the right leg, foot, and toes anxiety thinking about the filter
2:16-CV00214-PHX-DGC	Harvey, Sheryl	Matthews Bossier	Eclipse	Fracture, perforation of filter strut(s) into organs, PE, migration of filter to duodenum and lower lobe pulmonary artery
2:16-CV00215-PHX-DGC	Kestner, Johnny	G&K	Recovery	Severe and persistent chest pains, shortness of breath, severe and persistent pains in left arm and left leg, anxiety and mental anguish

2:16-CV00216-PHX-DGC	Hardenbrook, Beth	Goldenberg	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, several filter struts found to be outside of the caval wall
2:16-CV00217-PHX-DGC	Smith, Matthew	G&K	Meridian	Tilt with filter embedded in wall of the IVC
2:16-CV00218-PHX-DGC	Smith, Joyce	Matthews Bossier	Meridian	Perforation of filter strut(s) into organs, Device unable to be retrieved
2:16-CV00219-PHX-DGC	Levy, Patricia	G&K	G2	
2:16-CV00220-PHX-DGC	Terry, Cindy	Matthews Bossier	Recovery	Perforation of filter strut(s) into organs, migration of entire filter to heart
2:16-CV00221-PHX-DGC	Miller, Heather	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00223-PHX-DGC	Gore, Lishus Jr.	Matthews Bossier	Recovery	Tilt with filter embedded in wall of the IVC, migration of filter to junction of right atrium & vena cava
2:16-CV00224-PHX-DGC	Kimbro, Janet	Matthews Bossier	Eclipse	Fracture, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00225-PHX-DGC	Burns, Tiffany	Matthews Bossier	Eclipse	Fracture, perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved, a leg broke off and went to my heart
2:16-CV00226-PHX-DGC	Lopez, Tammy	Matthews Bossier	Recovery	Fracture, Perforation of Filter strut(s) into organs, Migration of entire filter to heart, Device unable to be retrieved
2:16-CV00227-PHX-DGC	Frame, Kathleen	Matthews Bossier	G2	Perforation of filter strut(s) into organs
2:16-CV00228-PHX-DGC	Henry, James E	Matthews Bossier	G2	Perforation of filter strut(s) into organs, recurrent PE
2:16-CV00229-PHX-DGC	Soliz, Ramiro	Matthews Bossier	Meridian	Device unable to be retrieved, Embedment
2:16-CV00231-PHX-DGC	Kowalczyk, Lucille A	Matthews Bossier	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be retrieved,

				bleeding
2:16-CV00232-PHX-DGC	Hodge, Daniel Jr.	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, tilt with filter emedded in wall of the IVC, device unable to be retrievable
2:16-CV00233-PHX-DGC	Morris, Cristal	Matthews Bossier	G2	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved.
2:16-CV00235-PHX-DGC	Tomlinson, Gary	McCarley		
2:16-CV00239-PHX-DGC	Williams, Michael	G&K	G2 Express	Severe and persistent chest pains, emotional distress and anxiety
2:16-CV00241-PHX-DGC	Owens, Margaret	Goldenberg	G2	Device unable to be retrieved
2:16-CV00242-PHX-DGC	Robinson, Gale	Goldenberg	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, legs of the filter extending beyond the medial wall of the vena cava
2:16-CV00246-PHX-DGC	Sepulveda, Chastity	Matarazzo	G2 Eclipse or Express per insertion records; Meridian per attempted removal records	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, filter struts appear to be perforated outside of vena cava in fluoroscopy images from 8/6/13 attempted removal despite no mention in radiology report
2:16-CV00247-PHX-DGC	Guarino, Michael L	Johnson	G2	Tilt with filter embedded in wall of the IVC, filter is noted with the tip near the renal vein IVC confluence. Several strokes extend beyond the margin of the inferior vena cava at its current narrowed state
2:16-CV00249-PHX-DGC	Kasler, Audrey	Johnson	Recovery	Fracture
2:16-CV00250-PHX-DGC	Mendes, Martha	LippSmith Anderson	Meridian	Filter removed per doctor's orders
2:16-CV00253-PHX-DGC	Bingham, Pamela	Johnson	Bard	Perforation of filter strut(s) into organs, three or four of

				the legs of the filter are penetrating through the caval wall. Tip of one leg lies anterior to the abdominal aorta. Two others are posterior to the IVC extending for a length of about 1-2 cm.
2:16-CV00255-PHX-DGC	Pugh, James E	Matthews Bossier	G2	Perforation of filter strut(s) into organs, Tilt with filter embedded in wall of the IVC, Migration- Retroperitoneum, duodenum, aorta, vertebral body; touching pancreas
2:16-CV00256-PHX-DGC	Hudson-Pierce, Mary	Johnson	Meridian	Fracture, fragment of IVC filter present in heart
2:16-CV00257-PHX-DGC	Nunn, Sonia	G&K	Eclipse	Severe and persistent chest pain, extreme anxiety, insomnia, persistent pain in left arm and leg
2:16-CV00259-PHX-DGC	Wilson, Ryan	Johnson	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00261-PHX-DGC	Harris, La'Trina	Johnson	Eclipse G2	Tilt with filter embedded in wall of the IVC
2:16-CV00262-PHX-DGC	Anastasoff, Nathan	Lopez	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00263-PHX-DGC	Tinlin, Debra	Lopez	Recovery	Fracture, Perforation of the filter strut(s), Device unable to be retrieved, Embolism of fractured struts to the right ventricle, basal interventricular septum, and lungs, causing a massive pericardial effusion, cardiac tamponade, cardiogenic shock, and multi-organ failure; penetration of several struts outside the lumen of the vena cava.
2:16-CV00264-PHX-DGC	Jensen, Wanda	G&K	Eclipse	Severe and persistent chest pains, severe anxiety attacks and emotional distress
2:16-CV00265-PHX-DGC	Valente-Kropf, Audrey	Lopez	Eclipse	Fracture, Bleeding, Migration of fractured strut to the heart, perforation the right ventricle and leading to

				hemopericardium with cardiac tamponade.
2:16-CV00266-PHX-DGC	Troulliet, David	Lopez	G2	Migration of entire filter to heart, filter tine perforation of the aorta, with subsequent development of an aortic pseudoaneurysm and aortic mural thrombus
2:16-CV00267-PHX-DGC	Schmuck, Eileen	Lopez	G2	Fracture; perforation of the caval wall, extending beyond the lumen
2:16-CV00268-PHX-DGC	Mixson, Joseph	Lopez	G2	Tilt with filter embedded in wall of the IVC; device unable to be retrieved; device migration down to the L2 disc space; protrusion of three to four legs outside the caval wall, with the struts projecting medially adjacent to the descending abdominal aorta and a single strut just posterior to the aorta
2:16-CV00269-PHX-DGC	Borden, George Borden, Melody	Lopez	Eclipse	<p>Tilt with filter embedded in wall of the IVC / Perforation of filter prongs through the vena caval wall, resulting in development of a right-sided retroperitoneal hematoma following removal of the device and subsequent bilateral DVT as a result of extensive luminal manipulation from the filter removal and compression of the vena cava by the hematoma.</p> <p>Plaintiff refers Defendants to his medical records for complete details of the injuries he has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, emotional and physical pain</p>

				<p>and suffering. Specifically, Plaintiff presented for planned retrieval of the filter prongs to be perforating through the IVC wall; after trying all viable options and requesting the help of a second surgeon, the filter ultimately could not be removed due to the filter's aggressive adherence to the IVC and heavy embedment of the nose cone into the vena cava, and the 21/2 hour procedure was aborted due to the prolonged time and the plaintiff's discomfort. A KUBx-ray on March 4, 2013 confirmed tilt of the filter. On April 5, 2013, Plaintiff consented to trying a bronchial forceps method, which was successful in retrieving the filter, although the filter was quite embedded and required significant pulling and pushing to ultimately be retrieved using a percutaneous method; a completion venogram showed a small area of vena irregularity at the location of the filter attachment. As a result, Plaintiff returned to the hospital on April 8, 2013, pale and weak, and was found to have developed a right-sided retroperitoneal hematoma, with narrowed contour of the IVC and mild hydronephrosis secondary to the mass effect, from a bleed associated with the vena caval perforation of the filter. He required two blood transfusions and was discharged on April 11, only to return again on April 15,</p>
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				having developed bilateral DVT, as a result of his extensive venous luminal manipulation for the recent filter removal and compression of the vena hematoma.
2:16-CV00270-PHX-DGC	Anderson, John	McCarley		
2:16-CV00274-PHX-DGC	Hahn, George M.	Terry Hoerman	Eclipse	Tilt with filter embedded in wall of the IVC, strut was twisted from the vein and relocated above filter in a salute position
2:16-CV00275-PHX-DGC	Kerbel, Paul	Terry	Denali	Device unable to be retrieved
2:16-CV00276-PHX-DGC	Lopez, Concepcion	Terry Hoerman	Denali	Shortness of breath and abdominal pain
2:16-CV00277-PHX-DGC	Ruck, David	Terry	Denali	Device unable to be retrieved
2:16-CV00282-PHX-DGC	Light, David	Terry Hoerman	G2 Express	Perforation of the filter strut(s) into organs, device unable to be retrieved
2:16-CV00285-PHX-DGC	Doze-Johnson, Shirley	Nolen	Meridian	On or about December 14, 2012, I underwent a removal surgery because I developed Staph aureus bacteremia, the IVC filter seated the bacteria
2:16-CV00286-PHX-DGC	Moody, Ronald Jr.	Lopez	Eclipse	Plaintiff has been advised that the device has moved and is blocking blood flow above his legs
2:16-CV00289-PHX-DGC	Kilcran, Patricia	Burke		
2:16-CV00294-PHX-DGC	Brown, Goldie	Lopez	Recovery	Fracture, device unable to be retrieved, a fractured strut migrated to the heart.
2:16-CV00303-PHX-DGC	Brewer, Naomi	LippSmith Anderson	Eclipse JS	Tilt with filter embedded in wall of the IVC, two legs of the IVC filter protrude into the aorta
2:16-CV00306-PHX-DGC	Copple, Gerald	Williams, Allen	Denali	Tilt with filter embedded in wall of the IVC, Device unable to be retrieved
2:16-CV00309-PHX-DGC	Paschal, Robert	Brenes	G2 X	Perforation of filter strut(s) into organs, tilt with filter

				embedded in wall of the IVC
2:16-CV00317-PHX-DGC	Blakley, Janice L	Dalimonte Toriseva	G2	Frature, perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00318-PHX-DGC	Hendrickson, Dawn M	Dalimonte Toriseva	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, perforation of the vena cava
2:16-CV00319-PHX-DGC	Mallory, Thomas <i>Admin. of the Estate of Paula Mallory</i>	Dalimonte Toriseva	G2	Bleeding, Perforation of the vena Cava
2:16-CV00320-PHX-DGC	Mills, Linda R	Dalimonte Toriseva	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, perforation of the vena cava
2:16-CV00321-PHX-DGC	Evers, Sara J	Dalimonte Toriseva	Recovery	Migration of entire filter to heart
2:16-CV00322-PHX-DGC	Nelson, Randy	Terry Hoerman	Eclipse	Fracture, tilt with filter embedded in wall of the iVC
2:16-CV00332-PHX-DGC	Dance, Shirley	Martin Arbon	Meridian	Fracture, perforation of filter strut(s) into organs, a strut migrated to plaintiff's heart
2:16-CV00333-PHX-DGC	Daniels, Dana	Martin Arbon	G2X	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00336-PHX-DGC	Fraser-Johnson, Bianca	Zappa Walsh Lengkeek		
2:16-CV00338-PHX-DGC	Froehlich, Dodi	Brenes	Recovery	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall fo the IVC, bleeding
2:16-CV00340-PHX-DGC	Allen, Valencia	Brenes	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00344-PHX-DGC	Ruden, Wayne	Ongaro Turner Bibbes Brownfield		
2:16-CV00355-PHX-DGC	Dewitt, Brent	Lopez	G2	Fracture, tilt with filter embedded in the wall of the IVC, device unable to be retrieved, perforation of filter

				legs through the inferior vena cava; migration of fractured strut(s) to the right ventricle of Plaintiff's heart
2:16-CV00386-PHX-DGC	Van Sciver, Barbara	DeGaris Seltz Fleishman	G2	Tilt with filter embedded in wall of the IVC, Device unable to be retrieved
2:16-CV00389-PHX-DGC	Vandervelden, Jillaine M.	Johnson Reed-Zaic	G2	Fracture, two wires, one lodged along the anterior wall of the right ventricle and the second extending from the posterior-inferior margin of the right ventricle through the intraventricular septum, through the left ventricle inferior wall and into the pericardial space.
2:16-CV00390-PHX-DGC	Mestre, Betty <i>Obo Eduardo Sanchez, deceased</i>	Johnson Reed-Zaic	G2	Dislodgement of the IVC filter with extrusion of the prongs outside the inferior vena cava with dislodgement of two prongs of the filter, one lodged in the right ventricular wall and the second one lodged in the small segmental branch of the left upper lobe
2:16-CV00392-PHX-DGC	Wallace, Maureen L.	Johnson Reed-Zaic	Meridian	Tilt with filter embedded in wall of the IVC
2:16-CV00393-PHX-DGC	Boudreau, Michelle	Johnson Reed-Zaic	G2 Express	Fracture, perforation of filter strut(s) into organs
2:16-CV00394-PHX-DGC	Wilt, Beau	Johnson Reed-Zaic	G2	Tilt with filter embedded in wall of the IVC, the legs are extending beyond the confines of the inferior vena cava are in the vicinity of the duodenum and aorta
2:16-CV00395-PHX-DGC	McLaine, Heather	Lopez	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00435-PHX-DGC	Williams, Kristy	Curtis	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00440-PHX-DGC	Day, Donna M	Nolen	Recovery	Perforation of filter strut(s) into organs

2:16-CV00445-PHX-DGC	Willmarth, Alexandra	Pearson	Eclipse	Fracture, perforation of two filter legs outside the vena cava wall
2:16-CV00446-PHX-DGC	Cain, Lance	Holland Crompton	Eclipse	Fracture / Perforation of filter strut(s) into organs / Migration of entire filter to heart / Tilt with filter embedded in wall of the IVC / Device unable to be retrieved / Bleeding Filter is still in place and plaintiff is at risk for all of the above
2:16-CV00470-PHX-DGC	Noa, Albert A	Boone Weisbrod Freeman		
2:16-CV00473-PHX-DGC	Johnson, Charles	Jackson	Recovery	Fracture, perforation of filter strut(s) into organs
2:16-CV00474-PHX-DGC	Booker, Sherr-Una	Lourie		
2:16-CV00477-PHX-DGC	Besaw, Jimmy John	Nations	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00479-PHX-DGC	Rose, Sharon Alethia	Nations	Eclipse	Device unable to be retrieved, tilting
2:16-CV00483-PHX-DGC	Olds, Jamison Wayne	Nations	G2	Perforation-struts in abdominal wall
2:16-CV00487-PHX-DGC	Eaton, Rebecca Eaton, Timothy	Nations	G2X	Perforation-struts extend beyond vena cava wall
2:16-CV00491-PHX-DGC	Fairman, Roberta	Nations	G2	Perforation-struts extend beyond vena cava wall
2:16-CV00494-PHX-DGC	Cundiff, Tony	Martin Arbon	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, migration of the filter within in IVC
2:16-CV00495-PHX-DGC	Holcomb, Tabitha Renee	Nations	Recovery	Fracture
2:16-CV00507-PHX-DGC	Lauhoff, Randall A.	Snapka Henderson Urquhart	Meridian	Device unable to be retrieved
2:16-CV00515-	Oliver, Audrey	Seldomridge	G2 Express	Fracture, device unable to be

PHX-DGC				retrieved, migration
2:16-CV00516-PHX-DGC	Browning, Teresa <i>obo Cora Browning</i>	Shaw Fishback Riley	Eclipse	Device unable to be retrieved, due to Plaintiffs medical condition.
2:16-CV00517-PHX-DGC	Flora, James	Shaw Fishback Riley	Denali	Shortness of breath and unable to walk far distances without staggering and falling. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail and cause additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop
2:16-CV00518-PHX-DGC	Spann, Dorothy <i>obo Simmy Hill</i>	Shaw Fishback Riley	Denali	The full extent of plaintiff's injuries are unknown at this time.
2:16-CV00519-PHX-DGC	Laufer, Evan	Shaw Fishback Riley	G2	Fractured, Device unable to be retrieved
2:16-CV00521-PHX-DGC	Perritt, Harold	Shaw Fishback Riley	Eclipse	Device unable to be retrieved
2:16-CV00523-PHX-DGC	Van Brocklin, Brian	Brenes	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00524-PHX-DGC	Reynolds-McDonnell, Theresa	Brenes	Eclipse	Fracture, perforation of filter strut(s) into organs
2:16-CV00525-PHX-DGC	Merrifield, Sarah	Brenes	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00534-PHX-DGC	Delbrugge, Ruth E.	Dalimonte Toriseva	G2	Perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00535-PHX-DGC	Tran, Adam T.	Dalimonte Toriseva	Recovery	Fracture, perforation of filter strut(s) into organs
2:16-CV00541-PHX-DGC	Fletcher, Carla	Lopez Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the

				IVC, perforation of the filter legs through the inferior vena cava; migration of fractured struts to the retroperitoneum and lung; perforation into aorta and heart; unable to retrieve fractured strut from the retroperitoneum; top hook of device is still missing
2:16-CV00542-PHX-DGC	Williams, Ronald	Lopez Lopez	Eclipse	Perforation of filter strut(s) into organs, plaintiff developed DVT post-implant of filter. CT scan demonstrated penetration of the filter legs into the retroperitoneal tissues with 2 legs approaching or abutting the aorta but not penetrating. Additionally, 1 leg was noted to cause erosion into a vertebral body.
2:16-CV00543-PHX-DGC	Witmer, Randy	Lopez Lopez	G2	Tilt with filter embedded in wall of the IVC/ Device unable to be retrieved/ perforation through vena cava wall/ slight migration within the inferior vena cava/
2:16-CV00546-PHX-DGC	Hans, Susan M.	Brenes	G2	Fracture, perforation of filter strut(s) into organs
2:16-CV00552-PHX-DGC	Jackson, Jai	Shaw Fishback Riley	G2	The full extent of plaintiff's injuries are unknown at this time.
2:16-CV00553-PHX-DGC	Robles, Lisa	Shaw Fishback Riley	Denali	Bleeding(urine), Swelling in area where filter was placed. Abnormal bleeding in urine. The full extent of plaintiff's injuries are unknown at this time.
2:16-CV00554-PHX-DGC	Turner, David	Shaw Fishback Riley	G2	Device unable to be retrieved
2:16-CV00555-PHX-DGC	Wagner, Brockett	Shaw Fishback Riley	Eclipse	Second Pulmonary embolism after the filter was implanted. The full extent of plaintiff's injuries are unknown at this time.

2:16-CV00556-PHX-DGC	Williams, Shanice	Shaw Fishback Riley	Eclipse	Perforation of filter strut(s) into organs, plaintiff developed DVT post-implant of filter. CT scan demonstrated penetration of the filter legs into the retroperitoneal tissues with 2 legs approaching or abutting the aorta but not penetrating. Additionally, 1 leg was noted to cause erosion into a vertebral body.
2:16-CV00557-PHX-DGC	Yarrington, Joseph	Shaw Fishback Riley	Meridian	Device unable to be retrieved, bleeding, blood clots
2:16-CV00558-PHX-DGC	O'Neil, Pamela	Tal Funk Branch	Eclipse	Device unable to be retrieved
2:16-CV00566-PHX-DGC	Ogden, Stephen	Skikos Mielke Skikos	Meridian	Device unable to be retrieved
2:16-CV00569-PHX-DGC	Valderas, Christopher Jowell	Martin Arbon	Denali	Device unable to be retrieved, post implantation thrombosis
2:16-CV00574-PHX-DGC	Ratz, Marilyn Ann	Martin Arbon	Eclipse	Tilt with filter embedded in wall of the IVC, perforation of struts through the IVC
2:16-CV00592-PHX-DGC	Hall, Gregory	Funk Branch Branch	Denali	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00596-PHX-DGC	Shinn, Michael L Shinn, Jennifer A	Chrisp	G2 Express	Fracture, tile with filter embedded in wall of the IVC, device unable to be retrieved - 1st attempt to retrieve was unsuccessful, bleeding, perforation of filter strut into spine
2:16-CV00598-PHX-DGC	Bond, Alana	Shah	Denali	Device unable to be retrieved
2:16-CV00600-PHX-DGC	Bailey, Rachel L	Moss Lenze Kamerrer	G2/Eclipse	Fracture, Perforation of Filter strut(s) into organs, Migration of entire filter to heart, Device unable to be retrieved
2:16-CV00605-PHX-DGC	Johnson, Joceylayn	Migliori Thompson	Denali	Tilt with filter embedded in wall of the IVC

		Duane Elswick-Hall		
2:16-CV00608- PHX-DGC	Agnelly, John	Funk Branch Branch	G2	Embedded in vein
2:16-CV00610- PHX-DGC	Duran, Melissa M.	Kaufman		
2:16-CV00612- PHX-DGC	Broecker, Jon	Funk Branch Branch	G2	Tilt with filter embedded in wall of the IVC, bleeding
2:16-CV00613- PHX-DGC	Hedge, Patricia	Funk Branch Branch	G2	Bleeding
2:16-CV00614- PHX-DGC	Underwood, Quanita	Funk Branch Branch	Meridian	N/A
2:16-CV00615- PHX-DGC	Crittendon, Ezekiel	Funk Branch Branch	Eclipse	Migration of entire filter to heart
2:16-CV00616- PHX-DGC	Smith, Darlene	Funk Branch Branch	Meridian	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, bleeding
2:16-CV00617- PHX-DGC	Narayan, Ashwin	Funk Branch Branch	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00620- PHX-DGC	Nelson, Jennie	Daly Leckman	G2	Perforation fo filter strut(s) into organs, devicwe unable to be retrieved, the device migrated to the origin of the right renal vein and multiple tines stick out of the IVC lumen extending into the right kidney and the right L2/3 intervertebral disc.
2:16-CV00621- PHX-DGC	Capriglione, David	LippSmith Anderson	G2	Device unable to be retrieved, plaintiff's filter is clogged, causing his inferior vena cava to close and collateral veins to form
2:16-CV00630- PHX-DGC	Hepler, Kim M	Peck Buttars	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00645- PHX-DGC	Christiansen, Martha Amy	Miller Vollersten	Recovery	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved,

				bleeding, struts of the filter extend beyond the lumen near the abdominal aorta.
2:16-CV00679-PHX-DGC	Satterwhite, Barabara	Seldomridge	Denali	Tilt with filter embedded in wall of the IVC
2:16-CV00687-PHX-DGC	Langford, Ava E. Brown, David R.	Rowland	G2 Express	Fracture, device unable to be retrieved, filter fragment remains within Plaintiff's body
2:16-CV00690-PHX-DGC	Alexander, Dorothy Kay	G & K	G2	Shortness of breath, lower abdominal pain, fainting spells, swelling in the legs, ankles, and abdomen, anxiety
2:16-CV00695-PHX-DGC	Haller, Sandra	Perkins	G2	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00701-PHX-DGC	Marshall, John	Langevin McSweeney	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00703-PHX-DGC	Cager, Bridget	Nolen, Rand	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00704-PHX-DGC	Duncan, Valerie A.	Nolen	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00715-PHX-DGC	Boutin, Carol	Shaw Fishback Riley	Eclipse	Bleeding, stomach pain
2:16-CV00716-PHX-DGC	Glant, Brenda	Shaw Fishback Riley	Eclipse	Discomfort and pain in the area of placement when standing or moving or turning. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail and cause additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop
2:16-CV00717-PHX-DGC	Nicholson, Rudolph	Shaw Fishback Riley	Meridian	Bleeding, filter became clogged causing blood clots, DVT and PE
2:16-CV00718-	Poole, Darrell	Shaw	Meridian	Bleeding, severe chest pain,

PHX-DGC		Fishback Riley		plaintiff also experiencing mental anguish and anxiety that the filter has failed or will fail
2:16-CV00719-PHX-DGC	Sankitts, Jeanie	Shaw Fishback Riley		
2:16-CV00728-PHX-DGC	Sourk, Patricia	DeGreeff Cartmell	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00739-PHX-DGC	Steinbrunn, Elmer	Hilton	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00742-PHX-DGC	Kennedy, Sheila	Toriseva	G2	Perforation of the vena cava, possible fracture of the IVC filter
2:16-CV00762-PHX-DGC	Meade, Gary	Seltz Fleishman	G2	Perforation of inferior vena cava
2:16-CV00763-PHX-DGC	Kreckel, John	Seltz Fleishman		
2:16-CV00771-PHX-DGC	Johnson, Vonneta	Martin Arbon	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00773-PHX-DGC	Knights, Judith	Martin Arbon	Eclipse	Fracture, migration of filter strut to the heart
2:16-CV00774-PHX-DGC	Peterson, Justin	Martin Arbon	Eclipse	Perforation of filter strut(s) into organs
2:16-CV00776-PHX-DGC	Whaley, Shirley	Martin Arbon	G2	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00778-PHX-DGC	Porter, Janice	Martin Arbon	G2x	Perforation of filter strut(s) into organs, device unable to be retrieved, migration of fractured filter strut to the heart
2:16-CV00779-PHX-DGC	Pratt, Tanner	Martin Arbon	Meridian	Fracture, tilting and 3 struts embedded in the Plaintiff's vena cava
2:16-CV00782-PHX-DGC	Jones, Doris	G&K	Eclipse	Jones, Doris GA 3/22/2016 2:16- cv-00782 Robert Boatman/Gallagher & Kennedy, P.A. Eclipse Fracture Yes

				Removed percutaneously
2:16-CV00786	Wolfe, Ronald A.	Mulvihill		
2:16-CV00788- PHX-DGC	Haremaker, Rebecca	Toriseva Law	G2 Express	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00789- PHX-DGC	Sekera, Mary B.	Dalimonte Toriseva	Eclipse	Fracture
2:16-CV00793- PHX-DGC	Watson, Glen	Gaddy Schultz	Meridian	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, perforation of vena cava. Abdominal pain, and mental anguish.
2:16-CV00797- PHX-DGC	Geoghegan, William	Lopez	G2	Tilt with filter embedded in wall of the IVC, struts of the filter separated in one area to 11mm apart, allowing clots to pass through; failed percutaneous retrieval attempt, with placement of a better-functioning filter above the first, in the suprarenal position; development of nonocclusive thrombus in the IVC, extending from mid- filter proximally above the filter, with incorporation of the filter struts into the thrombus
2:16-CV00802- PHX-DGC	Lucas, Amanda K.	Matthews Bossier	Recovery	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, embedment, migration to the pulmonary arteries
2:16-CV00804- PHX-DGC	Frain, Doris	Matthews Bossier	G2	Fracture, perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC
2:16-CV00805- PHX-DGC	Kaplysh, Barbara J.	Matthews Bossier	G2	Fracture, perforation of filter strut(s) into organs, migration to right lung base
2:16-CV00806-	McFalls, Lisa D.	Matthews	G2	Fracture, perforation of filter

PHX-DGC		Bossier		strut(s) into organs, migration embedment
2:16-CV00807-PHX-DGC	Spencer, Douglas	Matthews Bossier	Eclipse	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00808-PHX-DGC	Hoffman, Joan Marie	Matthews Bossier	Recovery	Fracture, migration--right ventricle, RLL lung, liver; and embedment in right ventricle wall
2:16-CV00809-PHX-DGC	Merced, Yandelli	Matthews Bossier	Meridian	Fracture, tilt with filter embedded in wall of the IVC, embedment
2:16-CV00810-PHX-DGC	Hutchens, Cassie L	Matthews Bossier	Meridian	Fracture, embedded in the base of the right ventricle
2:16-CV00811-PHX-DGC	Senger, Crystal	Matthews Bossier		
2:16-CV00812-PHX-DGC	Smith, Jessica	Matthews Bossier	Recovery	Fracture, embedment into IVC wall
2:16-CV00816-PHX-DGC	Turner, John T.	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, migration of a strut into the left renal vein and also toward the right renal vein
2:16-CV00817-PHX-DGC	Jones, Devin C.	Matthews Bossier	G2	Perforation of filter strut(s) into organs, migration of entire filter to heart
2:16-CV00818-PHX-DGC	Justice, Cedric	Matthews Bossier	G2	Perforation of filter strut(s) into organs
2:16-CV00819-PHX-DGC	Affonseca, Lavell	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, migration of filter to the IVC wall
2:16-CV00820-PHX-DGC	Taylor, Arrek P.	Matthews Bossier	G2	Perforation of filter strut(s) into organs, migration to the left renal vein
2:16-CV00821-PHX-DGC	Wood, John M.	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00823-PHX-DGC	Stroman, Deloris	Matthews Bossier	Eclipse	Perforation of filter strut(s) into organs
2:16-CV00824-PHX-DGC	Harrington, Lena	Matthews Bossier	Meridian	Perforation of filter strut(s) into organs
2:16-CV00825-PHX-DGC	Sowinski, Danielle	Matthews Bossier	Denali	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC,

				bleeding
2:16-CV00826-PHX-DGC	Revolinski, Rebecca R.	Matthews Bossier	Meridian	Tilt with filter embedded in wall of the IVC, migration of the filter to the IVC, and filter struts are bent
2:16-CV00829-PHX-DGC	McKinney, Heather	Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, severe fracture, strut migration and perforation within the caval wall and right kidney; migration from the suprarenal to the infrarenal IVC; failed percutaneous retrieval of device; and inability to retrieve the eight fractured struts
2:16-CV00830-PHX-DGC	Busser, Jason	Van Der Veer	G2	Fracture; perforation of filter strut(s) into organs; filter fractured during retrieval, causing strut(s) to migrate to heart, necessitating emergency open heart surgery
2:16-CV00831-PHX-DGC	Currie, Daniel	Matthews Bossier	G2	Perforation of filter strut(s) into organs, migration of entire filter to heart, embedment
2:16-CV00832-PHX-DGC	Tice, Shane	Plotkin	Recovery	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00837-PHX-DGC	Ohri, Puja	Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, failed retrieval attempt; migration of fractured strut, embedment in the L4 vertebral body and subsequent osteophyte development; retained fractured strut in the vertebrae
2:16-CV00842-PHX-DGC	Mulder, Michael	Lopez	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00844-	Svedise,	G&K	G2	Fracture, perforation of filter

PHX-DGC	Christopher			strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved, bleeding
2:16-CV00847-PHX-DGC	Stout, Shirley	Lopez	G2	Fracture, perforation of filter strut(s) into organs, rotation of the filter; migration outside the inferior vena cava into the abdominal aorta; extension of one leg into the infrarenal abdominal aorta and several other legs into the adjacent paracaval/perioaortic fat
2:16-CV00851-PHX-DGC	Hall, Joyce	Baughman Budd	Denali	Device unable to be retrieved
2:16-CV00853-PHX-DGC	Mulkey, Debra	DeGreef Cartmell	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00854-PHX-DGC	Montgomery, Danielle	DeGreef Cartmell	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00855-PHX-DGC	Germany, Donald	DeGreef Cartmell	Denali	Device unable to be retrieved, narrowing of the inferior vena cava caused by the IVC filter and residual thrombus within the IVC filter
2:16-CV00856-PHX-DGC	Tentori, Billie	DeGreef Cartmell	Eclipse	Tilt with filter embedded in wall of the IVC
2:16-CV00857-PHX-DGC	Pasierb, Joseph Jr.	DeGreef Cartmell	Eclipse	Perforation of filter strut(s) into organs
2:16-CV00866-PHX-DGC	Karlin, Ohnmar	Seldomridge	G2X	Fracture, perforation of filter strut(s) into organs
2:16-CV00869-PHX-DGC	Craig, Dustin	Voght		
2:16-CV00877-PHX-DGC	Mauldin, Melanie Buttermure	Lopez	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00878-PHX-DGC	Shelton, John	Lopez	G2 Express	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, slight migration within the inferior vena cava and penetration of fractured strut through the caval wall, with partial embedment in the

				aorta, requiring reconstruction of the inferior vena cava
2:16-CV00879-PHX-DGC	Hanratty, Lisa (formerly Himmler)	Lopez	Recovery	Device unable to be retrieved, one of the superior legs of the filter is in an inverted position within a small accessory right renal vein, indicating migration
2:16-CV00882-PHX-DGC	Fitch, Lisa	Lopez	Recovery	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV00883-PHX-DGC	Sessoms, Christy	Barreca Brenes	Meridian	Device unable to be retrieved
2:16-CV00887-PHX-DGC	Parsons, Latiesha	Johnson Reed-Zaic	G2	Tilt with filter embedded in wall of the IVC
2:16-CV00888-PHX-DGC	Senger, Crystal	Johnson Reed-Zaic		
2:16-CV00889-PHX-DGC	Wheeler, Marty Ray	Johnson Reed-Zaic	G2	Tilt with filter embedded in wall of the IVC, bleeding, leg of filter was embedded into lower intestine and back bone
2:16-CV00890-PHX-DGC	Bushman, Steven	Johnson Reed-Zaic	G2	Fracture, device unable to be retrieved, fractured strut embolized to the heart, unable to be removed
2:16-CV00891-PHX-DGC	Hoke, Terry	Lopez	Meridian	Fracture, bleeding, migration of fractured strut to the heart, transecting the right ventricle and causing a pericardial hematoma, requiring an emergency median sternotomy for removal of the fractured strut, surgical repair of the ventricle, and evacuation of the hematoma
2:16-CV00893-PHX-DGC	Hyde, Lisa	Lopez	G2	Fracture, migration of fractured strut to the right ventricle and multi-focal leg penetration through the inferior vena cava
2:16-CV00899-PHX-DGC	Grant, Michelle L.	Dalimonte Toriseva	G2 Express	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV00900-PHX-DGC	Brito, Sylvia	Dalimonte Toriseva	G2	Fracture, Perforation of filter strut(s) into organs

2:16-CV00901-PHX-DGC	Zamsky, Debra	Lopez	G2X	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, migration of filter, with embedment in spinal column; failed percutaneous retrieval attempt, requiring open removal
2:16-CV00902-PHX-DGC	Behlke, Cory	Lopez	Recovery	Fracture; migration of fractured strut to the lung, with further migration to the heart, and failed retrieval of fractured strut from heart.
2:16-CV00903-PHX-DGC	Lentz, Jennifer L.	Dalimonte Toriseva	G2	Fracture, perforation of filter strut(s) into organs, filter has fragmented into at least 5 pieces, 1 located in the aorta, 1 in the spine, and 1 pinching a nerve in her lower back. Physicians are unable to locate the remaining fragments
2:16-CV00904-PHX-DGC	Sherfy, Britt	Lopez	G2	Fracture, migration of fractured strut to the heart, with perforation of the left ventricle
2:16-CV00905-PHX-DGC	Fulton-Wolcott, Jennifer	Hammers, Jr.		
2:16-CV00906-PHX-DGC	Lisowski, Karin N.	Dalimonte Toriseva	Recovery	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, bleeding, perforation of the IVC caused massive bleeding, hematoma and duodenal mass which closed down the Plaintiff's intestine
2:16-CV00913-PHX-DGC	Boutin, Amanda Filed 4/1/16	Ledgard Goldwater	G2	Fracture, device unable to be retrieved
2:16-CV00918-PHX-DGC	McCabe, Shelly LaDawn Filed 4/4/16	Lopez	G2x	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, perforation into the right renal vein, right renal hilum, and toward the aorta; two failed attempts at

				percutaneous retrieval, requiring open surgical removal
2:16-CV00919-PHX-DGC	Kiscadden, Christine Filed 4/4/16	Lopez	Meridian	Fracture, failure to retrieve portion of the fractured arm due to full embedment in the caval wall; retained fragment within the blood vessel wall
2:16-CV00920-PHX-DGC	Engroff, Susan Mae	Lopez	G2	Fracture, perforation of filter strut(s) into organs, chronic embedment into the anterior caval wall with severe multifocal penetration into the retroperitoneum, with involvement of the adjacent vertebral body and retroarticular space
2:16-CV00921-PHX-DGC	Lusk, Beverly	Lopez	G2x	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00922-PHX-DGC	Painter, Judy Elaine	Lopez	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00923-PHX-DGC	Pearson, David	Daly Leckman	Recovery	Fracture, perforation of filter strut(s) into organs, plaintiff has a piece of filter imbedded in his lung
2:16-CV00925-PHX-DGC	Johnson, Jahnunice	Onstott Murray		
2:16-CV00926-PHX-DGC	Northern, Marcia	Onstott Murray		
2:16-CV00953-PHX-DGC	Edwards, Jeff M. obo Edwards, Florence	<i>Pro se</i>		
2:16-CV00955-PHX-DGC	Schneider, Tara	Terry	Meridian	Fracture, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV00965-PHX-DGC	Hutchins, Tricia	Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, embolization of fractured struts to the heart and lung; failed attempt at percutaneous retrieval, due to tilt and accumulation of fibrin surrounding the device;

				retained strut in lung
2:16-CV00966-PHX-DGC	Reck, Heidi	Lopez Daniel	G2	Fracture; Migration of fractured strut to the liver; Unable to retrieve the fractured strut, due to embedment in the hepatic parenchyma
2:16-CV00967-PHX-DGC	Alexander, Alex	Lopez	Eclipse	Fracture, tilt with filter embedded in wall of the IVC, possible fragments of filter remain in Plaintiff's body
2:16-CV00971-PHX-DGC	Gardner, Joedy	Lopez	G2 Express	Perforation of filter strut(s) into organs, perforation into the aorta, duodenum wall, and iliopsoas, accounting for a hematoma in the iliopsoas, requiring removal and replacement of the device
2:16-CV00987-PHX-DGC	Teague, Joyce	Skrabanek		
2:16-CV00988-PHX-DGC	Stringer, Michael D.	Farnolo		
2:16-CV01000-PHX-DGC	Kroeger, Thomas	Lopez	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, considerable tilt, with the apex buried into the caval wall and perforation of the struts through the IVC and extending into the L2 lumbar, causing secondary osseous sclerosis and lucency
2:16-CV01005-PHX-DGC	Callihan, Denine	Gaddy Schultz		
2:16-CV01006-PHX-DGC	Bradbury, Cynthia	Gaddy Schultz		
2:16-CV01007-PHX-DGC	Jolly, Denise	Gaddy Schultz		
2:16-CV01008-PHX-DGC	Morris, Jolene	Gaddy Schultz		
2:16-CV01009-PHX-DGC	Presswood, Roger	Gaddy Schultz	Recovery	Perforation of filter strut(s) into organs Chest pain and anguish over the fact the filter is still in my

				body. Please refer to medical records for complete details of injuries. I am not aware of all symptoms or conditions which may be related or resulted by my lawyer to determine this information.
2:16-CV01010-PHX-DGC	Rossmiller, Wanda	Gaddy Schultz		
2:16-CV01016-PHX-DGC	Pugh, James Edward	Seltz Fleishman		
2:16-CV01017-PHX-DGC	Grave, Elizabeth Ann	Seltz Fleishman		
2:16-CV01031-PHX-DGC	Mason, Vickie	Johnston	Recovery	Plaintiff is in the process of undergoing testing of her filter
2:16-CV01035-PHX-DGC	Johnson, Albert Johnson, Tracie	Peck Buttars	Recovery	Leg pain, shortness of breath and chest pain
2:16-CV01038-PHX-DGC	Wickstrom, Kari Rae	Johnson Becker	G2	tilt with filter embedded in wall of the IVC
2:16-CV01049-PHX-DGC	Brooks, Donna	Clinton	Eclipse	Fracture
2:16-CV01051-PHX-DGC	Bolton, Connie	Clinton	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV01054-PHX-DGC	Micek, Jennifer M. Micek, Joseph J.	Flaherty Szerlag	G2 Express	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV01077-PHX-DGC	Mitchell, Raymond Leon Mitchell, Judy	Nations	G2	Tilt with filter embedded in wall of the IVC
2:16-CV01078-PHX-DGC	Mangum, Prentiss E. Mangum, Sarah	Nations	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, multiple struts perforated vena cava and abdominal aorta
2:16-CV01079-PHX-DGC	Callaway, James Warner	Shaw Fishback Riley	Eclipse	Continous pain and swelling in right leg. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail and cause additional medical problem. The remaining extent of plaintiff's injuries are unknown at this time as they

				continue to develop.
2:16-CV01085-PHX-DGC	Crathers, Birdie	G&K	Denali	Filter remains in her body
2:16-CV01086-PHX-DGC	Czarnecki, Melissa	G&K		
2:16-CV01087-PHX-DGC	Andersen, James	G&K	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01088-PHX-DGC	Sheets, Tami	Hogins Moody	Meridian	Device unable to be retrieved
2:16-CV01089-PHX-DGC	Davis, Scott	G&K	G2	Fracture, device unable to be retrieved, a piece of filter was not removed, the leg of the filter
2:16-CV01090-PHX-DGC	McBride, Bernardette	G&K	G2	Plaintiff has implanted in him an IVC filter that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, is increasingly dangerous as it remains in his body
2:16-CV01091-PHX-DGC	Case, Timothy	G&K	Eclipse	Plaintiff has implanted in him an IVC filter that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, is increasingly dangerous as it remains in his body
2:16-CV01092-PHX-DGC	Buxbaum, Margaret B.	G&K	Eclipse	Plaintiff has implanted in her an IVC filter that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, is increasingly dangerous as it remains in her body
2:16-CV01093-PHX-DGC	Fish, David Burton	G&K	Recovery	Plaintiff has implanted in him and IVC filter that Bard represented and promoted to be safe and effective as a permanent device and that,

				contrary to Bard's representations, is increasingly dangerous as it remains in his body
2:16-CV01094-PHX-DGC	Bussell, Gary L.	G&K	G2	Device unable to be retrieved, plaintiff's doctor will not remove the IVC filter
2:16-CV01095-PHX-DGC	Docimo, Shelley A.	Lopez	G2	Tilt with filter embedded in the wall of the IVC, Device unable to be retrieved, Migration from infrarenal to suprarenal IVC; and three failed retrieval attempts, requiring lifelong anticoagulation
2:16-CV01096-PHX-DGC	Miller, Karen	Kell Ude		
2:16-CV01097-PHX-DGC	Prather, Marline	Lopez		
2:16-CV01099-PHX-DGC	Hall, Tiffany	Levy Gray White		
2:16-CV01100-PHX-DGC	White, Shawn White, Janet Lynn	Roslansky	G2	Tilt with filter embedded in wall of the IVC
2:16-CV01114-PHX-DGC	Dilworth, April	Ledgard	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV01115-PHX-DGC	Miller, Timothy	Langevin McSweeney	Simon Nitinol	Fracture (at least two), tilt with filter embedded in wall of the IVC, filter leg penetration into the retroperitoneum and aorta
2:16-CV01121-PHX-DGC	Malestky, John Malestky, Debbie	Schulte	Eclipse	Fracture, perforation of filter strut(s) into organs, bleeding
2:16-CV01131-PHX-DGC	Block, Deborah	Osborne	Meridian	Device unable to be retrieved
2:16-CV01132-PHX-DGC	Tsomos, Brigitte Tsomos, Georgios	McCarley		
2:16-CV01134-PHX-DGC	Lenners, Kevin	Tadtman Peterson Clevenger	Meridian	Tilt with filter embedded in wall of the IVC

2:16-CV01142-PHX-DGC	Adomnik, Mary Ann L.	Smith	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01143-PHX-DGC	Anderson, Dwain T. Anderson, Ellen	Smith	G2	Fracture, tilt with filter embedded in wall of the IVC, Other: strut fracture and migration
2:16-CV01144-PHX-DGC	Jernigan, Kelli	Smith	Denali	Filter moved allowing blood clots to pass
2:16-CV01145-PHX-DGC	Malott, Rita	Smith	Eclipse	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, one strut still in her body
2:16-CV01146-PHX-DGC	Rollins, Linda S.	Smith	Denali	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01149-PHX-DGC	Schaefer, Sharen	Smith	G2	Tilt with filter embedded in wall of the IVC
2:16-CV01150-PHX-DGC	Williams, Kristy	Smith	Bard Eclipse	Tilt with filter embedded in wall of the IVC, Device unable to be retrieved Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, mental anguish and fear of not knowing if or when the filter could move and kill me.
2:16-CV01151-PHX-DGC	Young, Phyllis	Smith	Recovery	Fracture, strut broke off
2:16-CV01153-PHX-DGC	Johnson, Julian E III <i>Obo Merrel Johnson</i>	Dalimonte Toriseva	G2	Tilt with filter embedded in wall of the IVC

2:16-CV01154-PHX-DGC	VanCleve, Angela	Dalimonte Toriseva	G2	Fracture, Perforation of filter struts into organs, Migration
2:16-CV01155-PHX-DGC	Ogidiagba, Carla	Dalimonte Toriseva	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV01157-PHX-DGC	Hoyle, Anna	Dalimonte Toriseva		
2:16-CV01180-PHX-DGC	Lockett, Bryan	Malik	G2	Fracture, perforation of filter strut(s) into organs, fractured strut has not been removed from right ventricle where it is still lodged after it broke off
2:16-CV01188-PHX-DGC	Belisle, Melissa	Diab Gomez Barton	Bard (specific type not listed)	Plaintiff states she has pain that gets worse at times and she feels like the filter is moving. She has pain in her inner thigh that travels up to her lower abdominal area.
2:16-CV01189-PHX-DGC	Fitzpatrick, Michael	Diab Gomez Barton	Denali	Plaintiff has an IVC filter implanted in his body that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, is increasingly dangerous as it remains in his body.
2:16-CV01193-PHX-DGC	Infante, Gretel	Bentley Zonies	Meridian	Failure unknown
2:16-CV01218-PHX-DGC	Carter, Melissa R.	Shaw Fishback Riley	Model unknown	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, sharp pains in the area where the filter is located
2:16-CV01219-PHX-DGC	Harbin, Raymond H.	Shaw Fishback Riley	Eclipse	Device unable to be retrieved, doctor told plaintiff too dangerous to attempt to remove filter
2:16-CV01202-PHX-DGC	Lopez, Mary H.	Lopez	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, penetration through inferior vena cava into L3 vertebral body, causing erosive-like change of the vertebrae and

				vascular irritation at the area of the filter strut's penetration into the vertebral body
2:16-CV01207-PHX-DGC	Menez, Donald	Baughman Budd	Eclipse	Device unable to be retrieved, pain, respiratory problems, shortness of breath
2:16-CV01220-PHX-DGC	Begley, Reba J.	Shaw Fishback Riley	Eclipse	Device unable to be retrieved, sharp pains in the area where filter was placed, developed broken bulging veins across her stomach
2:16-CV01221-PHX-DGC	Thomas, Vincent W.	Shaw Fishback Riley	Denali	Device unable to be retrieved; Plaintiff is worried that the filter may have fractured and become dislodged and will cause severe complications, injuries, or death. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail and cause additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop
2:16-CV01222-PHX-DGC	Henion, Robert	Baughman Budd	Meridian	Device unable to be retrieved
2:16-CV01223-PHX-DGC	Howard, Deborah	Baughman Budd	G2	Perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved, tilt, respiratory distress, severe pain
2:16-CV01238-PHX-DGC	McGhee, Kenya	Baughman Budd	Meridian	Perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV01239-PHX-DGC	Kiley, Nancy	Baughman Budd	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, one failed removal attempt prior to successful removal
2:16-CV01240-PHX-DGC	Pryor, Valerie	Baughman Budd	G2x	Migration of filter
2:16-CV01241-PHX-DGC	Sell, Tiffany	Baughman Budd	G2	Fracture, perforation of filter strut(s) into organs, device

				unable to be retrieved, the entire device was not able to be removed
2:16-CV01242-PHX-DGC	Martel, Donald <i>Executor estate of Martel, Shirley</i>	Baughman Budd	G2 Express	Pulmonary embolism, DVT, death
2:16-CV01243-PHX-DGC	Huff, Star	Baughman Budd	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC
2:16-CV01244-PHX-DGC	Carlson, Brittnee	Williams Allen	Meridian	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01254-PHX-DGC	Miner, Jeffrey S.	Sibbernson Berlowitz		
2:16-CV01252-PHX-DGC	Lewis, Carol	Lopez	G2	Fracture, embolization of fractured strut superior to the filter, chronically embedded; failed retrieval of fractured strut; retained fractured strut; and extensive thrombus within the indwelling filter, extending into the bilateral popliteal veins and causing severe venous obstruction and enlarged lumbar collateral
2:16-CV01257-PHX-DGC	Bunker, Andrea	Flaherty	G2	Fracture, Perforation of Filter strut(s) into organs, Migration of entire filter to heart, Device unable to be retrieved
2:16-CV01258-PHX-DGC	Albaum, Victor Honeyman, Rose M.	Lopez	Meridian	Fracture, perforation of filter strut(s) into organs, chronic embedment in caval wall, with penetration into the retroaortic area, slight migration of filter, and aborted retrieval attempt due to thrombus in the filter, which subsequently progressed to extensive vena caval and left iliofemoral thrombosis, requiring TPA thrombolysis and revascularization

2:16-CV01261-PHX-DGC	Brandi, Derek	Flaherty	Eclipse	Tilt with filter embedded in wall of the IVC, fracture of filter struts upon removal
2:16-CV01262-PHX-DGC	Kraft, Savanna	Flaherty	Denali	Tilt with filter embedded in wall of the IVC
2:16-CV01264-PHX-DGC	Vigil, David	Flaherty	Meridian	Tilt with filter embedded in wall of the IVC
2:16-CV01270-PHX-DGC	Bridgforth, Lawrence	Goldenberg	Eclipse	Filter migrated from original placement site and is situated abnormally low in the distal IVC. Several prongs of IVC filter have perforated the IVC wall and are outside the lumen of the IVC
2:16-CV01271-PHX-DGC	Woolley, David Woolley, Stacy	Cohn	G2	Fracture, perforation of filter strut into organs/ migration of entire filter to heart/device unable to be retrieved/ bleeding/tilt with filter embedded in wall of the IVC/ Open heart surgery to remove one strut from atrium: one strut lodged in lung: strut lodged in vena cava
2:16-CV01275-PHX-DGC	Powell, Clara Powell, Jeffrey	Kell Ude Aubuchon		
2:16-CV01276-PHX-DGC	Hearns, Daniel J.	Kell Ude Aubuchon		
2:16-CV01288-PHX-DGC	Gonzalez, Jose	Clinton	Recovery	Fracture, perforation of filter strut(s) into organs, migration of entire filter to heart, bleeding, made a 3" bloodclot in heart
2:16-CV01290-PHX-DGC	Jarecke, Ronald	Williams Domina		
2:16-CV01295-PHX-DGC	Borck, Julie Borck, James	DeGaris	Eclipse	Device unable to be retrieved
2:16-CV01298-PHX-DGC	Johnson, Joseph	DeGaris	Eclipse	Tilt with filter embedded in wall of the IVC
2:16-CV01299-PHX-DGC	Morehead, Mark Martn- Morehead, Angela C.	DeGaris	Meridian	Device unable to be retrieved

2:16-CV01301-PHX-DGC	Werst, Ramona Werst, David	DeGaris	Recovery	Fracture, Perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV01302-PHX-DGC	Taylor, James P.	Dalimonte		
2:16-CV01303-PHX-DGC	Stafford, Elizabeth J.	Dalimonte		
2:16-CV01308-PHX-DGC	Cramer, Justin	Dalimonte		
2:16-CV01309-PHX-DGC	Weakley, Brenda	Dalimonte		
2:16-CV01310-PHX-DGC	Henley, Camela M. <i>aka Henle, Camela</i>	Dalimonte		
2:16-CV01312-PHX-DGC	Hitch, Amy	Dalimonte		
2:16-CV01314-PHX-DGC	Jones, Jerry	Anderson Morris	DL900J	Device unable to be retrieved
2:16-CV01315-PHX-DGC	Sakosko, Everett Edward Jr.	Shaw Fishback Riley	GX	Plaintiff worried filter may have moved or fractured and become dislodged
2:16-CV01316-PHX-DGC	Whitmire, Jason	Tadtman Peterson Clevenger	G2X	Fracture, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01331-PHX-DGC	DiFranco, Carol	Osborne Schulte	G2	Perforation of filter strut(s) into organs, device unable to be retrieved, IVC filter erosion, extrusion of the struts into the aorta
2:16-CV01332-PHX-DGC	Rogers, Audrey	Osborne Schulte	Meridian	Device unable to be retrieved
2:16-CV01333-PHX-DGC	Baker, William Baker, Jacqueline	Osborne Schulte	G2 EXPRESS	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01334-PHX-DGC	Kornegay, Karen	Osborne Schulte	G2 express	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01338-PHX-DGC	Barton, Brett C.	G&K	Meridian	Caudal migration, plaintiff is in the process of obtaining medical records and will supplement as they are received
2:16-CV01339-PHX-DGC	Topping, Mark	G&K	Meridian	Plaintiff experiences pain and numbness in his arm and

				abdomen, fears it is because the device has migrated into his heart or fractured
2:16-CV01340-PHX-DGC	Van Heiningen, Robert	G&K	G2	Tilt with filter embedded in wall of the IVC, Device unable to be retrieved
2:16-CV01344-PHX-DGC	Steinmetz, Jane A.	LippSmith Anderson	G2	Device unable to be retrieved
2:16-CV01345-PHX-DGC	Landry, Calvin Landry, Christina	Peck Buttars	G2	Shortness of breath and chest pain
2:16-CV01347-PHX-DGC	Bryant, Jennifer	G&K	G2	Plaintiff has suffered from additional blood clots, restricted blood flow, and swelling of the legs that she attributes to the IVC filter
2:16-CV01349-PHX-DGC	Brown, Samantha	Liebhard		
2:16-CV01350-PHX-DGC	Norris, Ronda J.	G&K	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, filter may be causing clots
2:16-CV01351-PHX-DGC	Thompson, Shirley D.	G&K	G2	Plaintiff has implanted in her an IVC filter that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, is increasingly dangerous as it remains in her body
2:16-CV01352-PHX-DGC	Heitzler, Robert	Brenes	G2	Perforation of filter strut(s) into organs, migration of entire filter to heart, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01353-PHX-DGC	Gibson-Mason, Cynthia	Brenes	G2	Perforation of filter strut(s) into organs, device unable to be retrieved
2:16-CV01354-PHX-DGC	Badger, Anthony	Voght	Eclipse	Perforation of filter strut(s) into organs, bleeding
2:16-CV01355-PHX-DGC	Arnold, April	Voght	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, bleeding, embedding with resultant thrombosis

2:16-CV01356-PHX-DGC	DeChristofaro, Anthony	Voght	G2	Tilt with filter embedded in wall of the IVC, embedding with increase in clot problems
2:16-CV01357-PHX-DGC	Jones, Olan	Baughman Budd	Denali	Device unable to be retrieved, pain, death
2:16-CV01358-PHX-DGC	Lopez, Joe	Baughman Budd	Meridian	Bleeding
2:16-CV01359-PHX-DGC	Townley, Brenda	Baughman Budd	Meridian	Pulmonary embolism
2:16-CV01360-PHX-DGC	Reece, Shane W.	Voght	G2x	Device unable to be retrieved, thrombosed filter, thrombosis, caval thrombosis with increased clotting issues and lesions of lower extremities
2:16-CV01361-PHX-DGC	Williams, Anthony	Baughman Budd	G2	Migration of entire filter to heart, respiratory distress
2:16-CV01362-PHX-DGC	Crissey, Martin	Baughman Budd	Recovery	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01363-PHX-DGC	Hall, Matthew	Baughman Budd	G2	Migration of filter
2:16-CV01364-PHX-DGC	Harwell, Robert <i>Exector estate of Cindy Harwell</i>	Baughman Budd	Meridian	Malfunction allowing blood clots to travel to the brain resulting death
2:16-CV01365-PHX-DGC	Popp, Robert Popp, Ulla	Lopez	G2	Tilt with filter embedded in wall of the IVC, tine perforation into the inferior vena cava
2:16-CV01369-PHX-DGC	Collins, Suetta Lynn Collins, Christopher Wayne	Nations	G2	Perforation of vena cava wall
2:16-CV01371-PHX-DGC	Pipher, Maria Diane Pipher, Gary Antony	Nations		
2:16-CV01373-PHX-DGC	Emerson, Jeffrey Warren Emerson, Debra Maria	Nations	G2	Several legs extending beyond vena cava wall
2:16-CV01375-PHX-DGC	Gallant, Cheryl Ann	Nations	G2	Perforation of filter strut(s) into organs
2:16-CV01376-PHX-DGC	Cathcart, Krystal	Migliori Thompson Duane	Meridian	Tilt with filter embedded in wall of the IVC

2:16-CV01378-PHX-DGC	Heitzler, Robert Willaim Heitzler, Lisa Marie	Nations	G2	Perforation of filter strut(s) into organs / Migration of entire filter to heart / Tilt with filter embedded in wall of the IVC / Device unable to be retrieved Need to take blood thinners for the rest of my life. They can't take the filter out which causes anxiety, depression and fear of what could happen. Also unable to perform sexually.
2:16-CV01381-PHX-DGC	Philmore, Lawrence Philmore, Florence	Nations	G2	Perforation of vena cava wall
2:16-CV01382-PHX-DGC	Tangredi, Carl Paul Tangredi, Sherri Denise	Nations	Eclipse	Tilted with perforation of vena cava wall
2:16-CV01383-PHX-DGC	Taylor, Herman Jr. McGowan-Taylor, Irene	Nations	Eclipse	Significantly tilted with perforation of vena cava wall
2:16-CV01384-PHX-DGC	Townsend, Benjamin	Baughman Budd	Denali	Device unable to be retrieved
2:16-CV01385-PHX-DGC	Traylor, Vananda Gerrard	Nations	Eclipse	Perforation of vena cava wall
2:16-CV01386-PHX-DGC	Leist, Billy R.	Verhine	Meridian	Tilt with filter embedded in wall of the IVC
2:16-CV01387-PHX-DGC	Alexander, Clarissa	Mathews	Eclipse	Bleeding
2:16-CV01388-PHX-DGC	Lorring, Eva	Mathews	G2	Device unable to be retrieved
2:16-CV01391-PHX-DGC	Bisesi, Christine Ann	Pearson Johnson Fiebiger	G2	Device unable to be retrieved
2:16-CV01393-PHX-DGC	Sanchez, Thomas	Mathews		
2:16-CV01394-PHX-DGC	Denton, Gregory	Mathews		
2:16-CV01395-PHX-DGC	Waybright, Miriam Elizabeth	Nations	Eclipse	Perforation of vena cava wall
2:16-CV01396-	Brown, Patricia	Mathews	G2 Express	Device unable to be retrieved

PHX-DGC	K.		Vena Cava	
2:16-CV01397-PHX-DGC	Jones, Michael	Mathews		
2:16-CV01398-PHX-DGC	Golden, Tameka	G&K		
2:16-CV01399-PHX-DGC	Lona, Jose	Mathews		
2:16-CV01400-PHX-DGC	Scheib, Dustin	Nations		
2:16-CV01401-PHX-DGC	Hansen, Sandra	Lopez	G2	Fracture, embolization of fractured strut to the right lung; inability to retrieve the fractured strut; retained strut in the lung; perforation of the inferior vena cava, in proximity to the abdominal aorta; and replacement of the malfunctioning filter with a new filter
2:16-CV01402-PHX-DGC	Cribb, Chad Alan and Anne	Nations	G2X	Perforation of vena cava wall
2:16-CV01403-PHX-DGC	Scott, Ronald	Nations		
2:16-CV01404-PHX-DGC	Sutorus, Raymond	Tadtman Peterson Clevenger	Meridian	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01405-PHX-DGC	Jacobi, Anthony Edward	Nations	Eclipse	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved Stress, Anxiety
2:16-CV01406-PHX-DGC	Malanga, Dolores	Mathews		
2:16-CV01412-PHX-DGC	Simon, James	Lopez	Recovery	Fracture, device unable to be retrieved, retraction of the filter legs; extraluminal projection of the filter struts through the IVC ; unsuccessful retrieval attempt; total occlusion of the filter, causing the IVC to be

				completely thrombosed and collapsed, limiting blood flow and resulting in a need for possible IVC recanalization; and retained fractured strut.
2:16-CV01415-PHX-DGC	Monroe, Diane Monroe, Jerry	Angelo & White		
2:16-CV01417-PHX-DGC	Hop, Robin Lynn	Riley & Jackson		
2:16-CV01421-PHX-DGC	Doorn, Julie A.	Warner Law Offices	Eclipse	Device unable to be retrieved, caudal filter migration and fibrin cap.
2:16-CV01425-PHX-DGC	Varner, Casey	Lowe Law Group	Eclipse	High blood pressure, chest pain, and psychological and mental distress
2:16-CV01433-PHX-DGC	Carnes, Lee Ann	Tadtman Peterson Clevenger	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01463-PHX-DGC	Wilson, Jeffrey Powell	Babbitt & Johnson		
2:16-CV01464-PHX-DGC	Eason, Robert	Babbitt & Johnson		
2:16-CV01483-PHX-DGC	Andrews, Robert and Joana	Lopez	G2X	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, perforation of IVC and renal vein, complete embedment of the nosecone of the filter in the caval wall, requiring open abdominal retrieval and repair of a serosal tear, and post-operative complications including acute respiratory failure, acute kidney injury, hypotension, ongoing tachycardia, and slight hypoxia
2:16-CV01488-PHX-DGC	Knapp, Danielle and Wesley	McEwen Law Firm Ltd	G2	Perforation of filter strut(s) into organs, blood clots into lungs despite filter
2:16-CV01497-PHX-DGC	Isaac, Linda	Ben Martin	G2	Fracture, the filter's struts have perforated the vena cava, two struts are fractured
2:16-CV01514-	Austin, Melvin	Langevin	Simon	Tilt with filter embedded in

PHX-DGC	Austin, Jennifer	McSweeney	Nitinol	wall of the IVC, device unable to be retrieved (1st implant), chronic occlusion of infra-renal IVC by thrombus surrounding the tilted IVC filter
2:16-CV01517-PHX-DGC	Gillespie, Jennifer Thompson, Leeland	Langevin McSweeney	Eclipse	Tilt with filter embedded in wall of the IVC, IVC filter affecting renal flow
2:16-CV01518-PHX-DGC	Swan, Ricky	Shaw Fishback Riley	G2	Plaintiff has suffered from swelling in his legs, poor circulation of blood flow, breathing problems, heart problems, and been diagnosed with additional blood clots. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop.
2:16-CV01520-PHX-DGC	Utter, Terri Sue	Shaw Fishback Riley	Denali	Bleeding, Dr. had hard time removing filter and second dr. had to assist. Said had trouble removing because the filter did not close properly and he also saw a tear from the filter and some bleeding
2:16-CV01536-PHX-DGC	Bechard, Rebecca Wilder, Travis	Daly Leckman		
2:16-CV01543-PHX-DGC	Johnson, Janine	Gaddy Schultz		
2:16-CV01561-PHX-DGC	Ibarra, Rebecca	Williams Allen	G2	Perforation of filter strut(s) into organs, device unable to be retrieved, filter embedded in the caval wall or penetrating through it, there is no easy way to retrieve it
2:16-CV01562-PHX-DGC	Dry, Wanda <i>Administrator of the Estate of</i>	Seldomridge	Meridian	Migration of entire filter to heart

	<i>Joanna Settles</i>			
2:16-CV01573-PHX-DGC	Wilson, Barbara	Hilton	Meridian	Fracture. As a result of the injuries caused by the fracture of two filter struts, I have continued pain and suffering, disability, mental anguish, and loss of capacity for the enjoyment of life, and the expense of medical care. I am in constant fear and suffer from anxiety that the fractured struts will migrate, causing serious injury or death.
2:16-CV01576-PHX-DGC	Ward, Adrienne	Daly Leckman	G2	Fracture, device unable to be retrieved
2:16-CV01578-PHX-DGC	Warren, Penny	Gallagher, Michael T.		
2:16-CV01581-PHX-DGC	Roberts, Glenda F <i>Administrator of the Estate of Gary F. Hamilton</i>	Matthews Bossier	Recovery	Recurrent pulmonary embolism and venous thrombosis resulting in death
2:16-CV01600-PHX-DGC	Rogers, Criss L.	Nolen Fleming Jez	Denali	Migration of entire filter to heart
2:16-CV01607-PHX-DGC	Breitschuh, Diana <i>Administrator of the Estate of Robert D. Breitschuh</i>	Bossier Matthews	Eclipse	Caval thrombosis
2:16-CV01615-PHX-DGC	Schwartz, Susan	Johnson		
2:16-CV01625-PHX-DGC	Lutz, Cally	Kidd Perdue Winegar		
2:16-CV01632-PHX-DGC	Toms, Richard	Elliott		
2:16-CV01633-PHX-DGC	Weller, Jay Bee and Norma	Elliott		
2:16-CV01634-PHX-DGC	Dawidowicz, James	Elliott		
2:16-CV01637-PHX-DGC	Campbell, Bryan	Buttars	Meridan® Vena Cava Filter	Severe and persistent chest pain and shortness of breath.

2:16-CV01648-PHX-DGC	Sapp, Karen	Buttars	Recovery	Bleeding, severe and persistent chest pain, shortness of breath, sharp pain in lower pelvic region at the implant site
2:16-CV01656-PHX-DGC	McCallister, Frances	Van Wey	Denali	Right sided neck palpitations where the IVC filter was removed
2:16-CV01657-PHX-DGC	Young, Steve D.	Waters	G2	Fracture / Perforation of filter strut(s) into organs Perforation of aorta and retrpoeritoneum. Damage caused by explant.
2:16-CV01659-PHX-DGC	Johnson, Trudy and Chris	Seldomridge		Tilt with filter embedded in wall of the IVC.
2:16-CV01660-PHX-DGC	Traughber, Vickie J. and Robert	Seldomridge	G2	Device unable to be retrieved
2:16-CV01677-PHX-DGC	Blair, Edward	Peck Buttars	Denali	Chest pain, shortness of breath, swelling in legs, and fatigue
2:16-CV01678-PHX-DGC	Bunch, Penny and Jeffrey	Peck Buttars	G2	Severe and persistent chest pain, shortness of breath, and myocardial infarction
2:16-CV01681-PHX-DGC	Klock, December Faye	Martin	Eclipse	Migration of entire filter to heart / Other failure mode(s): Migration to renal veins and inability to engage hook Chest pains, headaches, skin sores, skin peeling anxiety, missed bonding with newborn after delivery
2:16-CV01685-PHX-DGC	Benson, Jackson	Martin	Beard Recovery	Fracture / Perforation of filter strut(s) into organs Mr. Benson experienced pain and swelling in his lower extremities.
2:16-CV01692-PHX-DGC	Malloy, Tonia and Jeremy	Christian	G2x	tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01693-PHX-DGC	Brondou, Angela and Gerry	Christian	Eclipse	Tilt with filter embedded in wall of the IVC
2:16-CV01722-	Smith, Jason	Lopez		

PHX-DGC				
2:16-CV01726-PHX-DGC	Keel, Jeff	Gaddy Schultz		
2:16-CV01739-PHX-DGC	King, Adam	Hammers Pendergrass		
2:16-CV01741-PHX-DGC	Naylor, Tracy and James Gregory	Roslansky	G2	Device unable to be retrieved, struts extruding 3 or 4 mm into IVC wall
2:16-CV01749-PHX-DGC	Richards, Jennifer A	Kushlefsky	Recovery	Fracture, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV01750-PHX-DGC	St. John, Edward	Hilton	DL900J	<p>Filter is tilted and one of the legs projects posterior to the IVC.</p> <p>As a result of the tilt and perforation of my inferior vena cava by the Bard IVC Filter, I have continued pain and suffering, disability, mental anguish, and loss of capacity for the enjoyment of life, and the expense of medical care. I have chest pain, thigh pain, anxiety attacks, shortness of breath attributed to my anxiety attacks, and constant worry that filter is a ticking time bomb that will fracture, migrate, or otherwise fail and cause me serious physical injury and or my death.</p>
2:16-CV01754-PHX-DGC	Jackson, Marilyn Rose	Johnson Babbitt & Johnson		
2:16-CV01757-PHX-DGC	McKinnie, Jerry and Teresa Beard	Lopez	G2	Plaintiff will require lifelong monitoring of his filter to make sure it is not about to fracture, perforate, migrate, or malfunction in some way, creating a life-threatening situation for Plaintiff. Plaintiff

				has to live with constant worry and anxiety about the state of his health related to his IVC filter
2:16-CV01758-PHX-DGC	Leyva, Elizabeth and Juan	Buttars Peck	G2	Tilt with filter embedded in wall of the IVC, device unable to be retrieved, severe and persistent chest pain, shortness of breath, groin pain, restricted blood flow, possible amputation of leg.
2:16-CV01764-PHX-DGC	Bak, Thomas	Johnson Babbitt & Johnson		
2:16-CV01765-PHX-DGC	Pritchett, Amanda	Johnson Babbitt & Johnson		
2:16-CV01766-PHX-DGC	Butler, Heather	Mokwa		
2:16-CV01775-PHX-DGC	Bernstein, Helen	Johnson		
2:16-CV01776-PHX-DGC	Crowe, Lorene	Johnson	Eclipse	Perforation of filter strut(s) into organs, device unable to be retrieved, filter migration. Please refer to medical records for complete details of injuries. I am not aware of all symptoms or conditions, which may be related or resulted from the implantation of the filter and I am relying on the experts that will be retained by my lawyer to determine this information.
2:16-CV01777-PHX-DGC	Taylor, Michael	Johnson Babbitt & Johnson		
2:16-CV01779-PHX-DGC	Hill, George and Sharon	Johnson		
2:16-CV01780-PHX-DGC	Caldwell, Joseph	Johnson		
2:16-CV01789-PHX-DGC	Raby, Sharon and Tony	Johnson		
2:16-CV01797-	Estrada,	Johnson		

PHX-DGC	Jacqueline B			
2:16-CV01798-PHX-DGC	Hall, Danny and Judith	Johnson		
2:16-CV01799-PHX-DGC	Houston, Amanda	Johnson		
2:16-CV01806-PHX-DGC	Ponder, Julie Ann	Shaw Fishback Riley	Meridian	Plaintiff is experiencing physical stress, mental anguish, and anxiety that the filter has failed, fractured or will fail causing additional medical problems
2:16-CV01807-PHX-DGC	Navratil, Sue Anne	Gallagher		
2:16-CV01811-PHX-DGC	Rivers, Joseph and Dianca	McGartland	G2	Device unable to be retrieved, IVC thrombosis then DVT, pulmonary embolism x4 episodes
2:16-CV01813-PHX-DGC	Bobo, Renneaka	Fishback, Riley, Shaw	G2	Plaintiff understands that the filter is embedded in a vein and removing the filter would cause serious complications. Plaintiff is experiencing chest pain and recently had a blood clot in her leg. Also experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems, remaining extent of injuries are unknown at this time as they continue to develop
2:16-CV01814-PHX-DGC	Lockwood, Teresa	Fishback, Riley, Shaw	Model unknown	Severe pain in the area where the filter was implanted, chest pain and pain beside and underneath her breasts. Also experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems
2:16-CV01815-PHX-DGC	Witt, Jessica	McCarley		
2:16-CV01819-PHX-DGC	Ford, Charles and Sara	Johnson		
2:16-CV01820-PHX-DGC	Fletcher, Louis and Roxanne	Johnson		
2:16-CV01821-	Hayama,	Johnson		

PHX-DGC	Charlene and Roy			
2:16-CV01822-PHX-DGC	Lee, Amanda	Barton, Diab, Gomez	Denali	Pltf. had an IVC filter implanted in her body that Bard represented and promoted to be safe and effective as a permanent device and that, contrary to Bard's representations, was increasingly dangerous as it remained in her body. Pltf underwent multiple surgeries to repair the damage she sustained during the procedure to remove the Bard device from her body.
2:16-CV01835-PHX-DGC	Allen, Marchita Allen, Joel	Brenes	Meridian	Fracture / Perforation of filter strut(s) into organs
2:16-CV01836-PHX-DGC	Agee, Charlene	Lopez	G2	Device unable to be retrieved, plaintiff will require lifelong monitoring of her filter to make sure it is not about to fracture, perforate, migrate, or malfunction in some way, creating a life-threatening situation for plaintiff, plaintiff has to live with constant worry and anxiety about the state of her health related to her IVC filter
2:16-CV01838-PHX-DGC	Watson, William L.	Johnson		
2:16-CV01849-PHX-DGC	Stith, Andrea	Presby	Simon Nitinol	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, erosion retroperitoneal abscess, erosion through the vena cava
2:16-CV01852-PHX-DGC	Carter, Ashley M.	Bohrer	G2 or Recovery	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, one prong from filter had to be left in place due to inability to retrieve
2:16-CV01858-PHX-DGC	Smith, Victoria	Pendergrass Hammers		

2:16-CV01859-PHX-DGC	Manis, Jeffrey	Pendergrass Hammers		
2:16-CV01861-PHX-DGC	Price, Anitra	Pendergrass Hammers		
2:16-CV01862-PHX-DGC	Bartolini, Jesse	Pendergrass Hammers		
2:16-CV01864-PHX-DGC	Farmer, Tammy Lynn Farmer, Wayne	Pendergrass Hammers		
2:16-CV01865-PHX-DGC	Konstalid, Penny Konstalid, James	Pendergrass Hammers		
2:16-CV01868-PHX-DGC	Campbell, Julius E. <i>Executor of the estate of Jeanne Campbell</i>	Lopez	G2	Fracture, perforation of filter strut(s) into organs, device unable to be retrieved, migration of the filter within the inferior vena cava, fracture and displacement of a strut along the left of the inferior vena cava at a 90 degree angle, protrusion of struts into the inferior vena cava and left renal vein, development of extensive bilateral pulmonary emboli, which led to a non-ST-elevation MI, as the displaced filter was a significant source of thrombus and not providing complete coverage of the inferior vena cava
2:16-CV01885-PHX-DGC	Hamilton, Jacqueline	Shaw Fishback Riley	Eclipse	Bleeding, plaintiff experiencing spotting, pain and discomfort
2:16-CV01886-PHX-DGC	Jobe, Reagan Jobe, Jaleesa	Lopez	G2	Fracture, perforation of the filter strut(s) into organs, and bleeding. Perforation of IVC and duodenum, causing pericarditis and renal infection; fracture, with embolization of strut into the lung, causing pericardial effusion; further fracture of the fragment; retained fragments, which could not be located in the most recent scan, suggesting

				further migration.
2:16-CV01891-PHX-DGC	Robinson, Charles	Merrigan	Meridian	Tilt with filter embedded in wall of the IVC. IVC thrombosis; migration of filter to eccentric position. Chest pain and shortness of breath.
2:16-CV01892-PHX-DGC	Adams, Alana Darlene Adams, Christopher Paul	Nations	Recovery	Device unable to be retrieved, filter tip perforated vena cava. Stress; anxiety; numbness/pain in hands and feet.
2:16-CV01905-PHX-DGC	Gottlieb, Rita <i>Obo Bernard Gottlieb</i>	Johnson		
2:16-CV01917-PHX-DGC	Perez, Radames <i>Obo Regina R. Perez</i>	Johson		
2:16-CV01935-PHX-DGC	Powell, Johnnesia	Roslansky		
2:16-CV01940-PHX-DGC	Benanti, Frank	Gaddy Shultz		
2:16-CV01951-PHX-DGC	Geiger, Timothy	Seldomridge	Eclipse	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device uanble to be retrieved
2:16-CV01952-PHX-DGC	Larson, Mary Larson, David	Seldomridge	Meridian	Not applicable
2:16-CV01953-PHX-DGC	Hardwick, Charles and Oma	Seldomridge	Denali	Device unable to be retrieved
2:16-CV01955-PHX-DGC	Sasko, Angela	Plotkin	Eclipse	Tilt with filter embedded in wall of the IVC, device unable to be retrieved. Back pain, abdominal pain, sharp pain when breathing, unable to give birth, and chest pain.
2:16-CV01957-PHX-DGC	Diven, Katherine	Plotkin	Bard G2	Fracture / Migration of entire filter to heart / Strut migrated to heart, removed with open heart surgery
2:16-CV01958-PHX-DGC	O'Regan, Brian	Anderson LippSmith	G2	Device unable to be retrieved. Ineffective filter; irretrievable and occluded filter; fear of further complications such as migration and/or fracturing; fear of untimely death due to the filter.

2:16-CV01970-PHX-DGC	Hill, Abbie Nickerson, Stephen	Lopez	G2	Fracture, perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved, two failed retrieval attempts, due to tilt and embedment in the caval wall; perforation through the caval wall into the psoas muscle and duodenum, causing chronic pain; fracture, with embedment of the fractured struts into the caval wall; and retained filter and strut, embedded in caval wall
2:16-CV01971-PHX-DGC	Willis, Craig	Anderson Morris	Bard Recovery	Fracture / Device unable to be retrieved As a result of removal surgery, developed an unidentified infection and was sick for 6 weeks. As a result of the infection and surgery, Plaintiff's kidneys have suffered protein loss and Plaintiff is currently under the care of a nephrologist for treatment.
2:16-CV01976-PHX-DGC	Toth, Michael E.	Nolen	G2	Tilt with filter embedded in wall of the IVC Device unable to be retrieved Emotional stress due to position and location of filter which is causing kidney failure and possible loss of kidney
2:16-CV01989-PHX-DGC	Thomas, William T.	Fennell	Denali	Bleeding.
2:16-CV01990-PHX-DGC	Powell, Emma and Richard W.	Fennell	Denali	Concerned about the failure rate of the IVC filter which has caused mental anguish.
2:16-CV01993-PHX-DGC	Harris, Renee	Martin	Bard Meridian	Did not prevent blood clots to lungs

				I am fearful of breakage and migration. The filter is defective because it did not prevent blood clots in my lungs in 2014 and might not prevent further clots.
2:16-CV02006-PHX-DGC	Marsh, Donald and Roberta	Roslansky		
2:16-CV02036-PHX-DGC	Collins, Juli	Stackhouse	G2	Perforation of filter strut(s) into organs, device unable to be retrieved, Post-Implant DVT.
2:16-CV02039-PHX-DGC	Thomas, Kwame	Fleishman, Seltz		
2:16-CV02040-PHX-DGC	Murriel, Clyde	Fennell	Bard Eclipse	Varicose veins of the lower extremities with ulceration due to chronic venous stasis wound: Lower leg Deep Vein Thromboembolism (DVT)
2:16-CV02056-PHX-DGC	Gordon, Veronica	Johnson		
2:16-CV02060-PHX-DGC	Marsanick, John <i>Obo Deborah Marsanick, deceased</i>	Lopez	Meridian	The filter allowed clots to pass through to the lungs, causing cardiopulmonary arrest and death
2:16-CV02061-PHX-DGC	Hayes, Curley Gene	Johnson		
2:16-CV02064-PHX-DGC	Geiger, Timothy	Aubuchon, Kell, Ude	Eclipse	Perforation of filter strut(s) into organ / Tilt with filter embedded in wall of the IVC / Device unable to be retrieved
2:16-CV02071-PHX-DGC	Carpenter, Charletta	Mielke, Skikos		
2:16-CV02075-PHX-DGC	Terry, William	Hoerman Terry	Bard Eclipse Vena Cava Filter - Femora	Perforation of filter strut(s) into organs / Tilt with filter embedded in wall of the IVC / Migration of filter Please refer to Plaintiff's medical records for details regarding physical injuries which are related to the BARD IVC filter. Plaintiff has suffered from additional

				injuries but not limited to, physical pain and suffering, discomfort and emotional distress.
2:16-CV02076-PHX-DGC	Campeaux, Sharon	Goetz	G2	Device unable to be retrieved
2:16-CV02078-PHX-DGC	Zimmerman, Carol Ann and Michael	Ferraro	Meridian	Emotional Distress and Anxiety/Recurrent clots
2:16-CV02087-PHX-DGC	Doggett, Kathleen	Michael T Gallagher		
2:16-CV02088-PHX-DGC	Muniz, Maria and Perez, Jose	Michael T Gallagher		
2:16-CV02089-PHX-DGC	Anderson, Claus and Joan	Michael T Gallagher		
2:16-CV02090-PHX-DGC	Buchanan, Barbara and James	Michael T Gallagher		
2:16-CV02091-PHX-DGC	Brown, Shannon	McCarley		
2:16-CV02098-PHX-DGC	Byrne, Teresa	McCarley	Meridian	Device unable to be retrieved
2:16-CV02099-PHX-DGC	Cekavic, Lorie and Steven	McCarley		
2:16-CV02101-PHX-DGC	Nunez, Irma	McCarley		
2:16-CV02102-PHX-DGC	Cooper, Mary	McCarley	G2	Device unable to be retrieved
2:16-CV02103-PHX-DGC	Bilbeck, David	McCarley		
2:16-CV02104-PHX-DGC	Hammond, Lorella	McCarley	G2	Device unable to be retrieved / Scared tissue in surgery site that is causing blood to clot up in the area Constant pain in my abdominal area, ER visits due to chronic pain missing work due to depression from the pain that will not go away
2:16-CV02118-PHX-DGC	Meinholdt, Barbara	Roslansky		
2:16-CV02122-PHX-DGC	Garrett, Randy	McCarley	Eclipse	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved

2:16-CV02123-PHX-DGC	Hill, David and Victavia	McCarley		
2:16-CV02124-PHX-DGC	Hinojosa, Venessa	McCarley	G2	I feel a popping in me and it hurts. I get a lot of chest pains at times one side of my body goes numb.
2:16-CV02128-PHX-DGC	Leary, Audrey and Kevin	McCarley	G2	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved
2:16-CV02129-PHX-DGC	Lyle, Jack and Kathi	McCarley	G2	<p>Device unable to be retrieved / caused formation of clots from the IVC filter down both branches of (iliac) veins to my ankles resulting in bilateral DVTs. Lower body edema. Leg pain</p> <p>Bilateral DVTs from the filter to both ankles, impaired body circulation, lower body pain, development of bilateral varicocoeles. Lower extremities edema, worsened ED. Fear and uncertainty on my part and my family's part concerning filter failure.</p>
2:16-CV02130-PHX-DGC	Lynch, Lina	McCarley	G2	
2:16-CV02135-PHX-DGC	Martin, Patrick	McCarley		
2:16-CV02136-PHX-DGC	Coats, Russell	Johnson		
2:16-CV02145-PHX-DGC	Orange, Linda	Allen	Bard G2 X	
2:16-CV02146-PHX-DGC	Mahoney, Therese	Elliott	Denali	
2:16-CV02147-PHX-DGC	Mathews, Jamie	Elliott	Denali	
2:16-CV02148-PHX-DGC	Armbruster, Jarrod	Cartmell	Meridian	Device unable to be retrieved / Chronic Thrombus, Chronic DVTs, Collateral Veins, Caput Medusae Chest and stomach deformity due to veins, weakening of heart an issue I did not have prior to

				<p>the IVC filter implant.</p> <p>Plaintiff refers Defendants to his medical records for complete details of his injuries he has suffered stemming from Defendants' IVC Chronic DVTs, Collateral Veins and Caput Medusae. Deformed chest and stomach due to veins, weakened heart inability to remove IVC filter, pain suffering and mental anguish due to the high failure rates of Bard IVC filters.</p>
2:16-CV02157-PHX-DGC	Mullins, Clifford and Heather	Guarnieri	G2	<p>Fracture, perforation of filter strut(s) into organs, device unable to be retrieved, filter struts fractured and became embedded in heart and lung. A strut remains embedded in lung and is unable to be removed</p>
2:16-CV02159-PHX-DGC	England, William Thomas	Goldenberg	G2	<p>Frequent medical monitoring required. Plaintiff now requires constant medical monitoring. Plaintiff lives with the daily fear that the filter may malfunction, knowing that if it does, little can likely be done.</p>
2:16-CV02161-PHX-DGC	Plantrich, Kimberly	Stackhouse	Recovery	Perforation of filter strut(s) into organs, migration.
2:16-CV02166-PHX-DGC	Cox, Larry and Dorothy	Johnson		
2:16-CV02190-PHX-DGC	Coleman, Stephanie	Curtis	Bard G2	<p>Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to; severe and persistent chest</p>

				pain and shortness of breath and fear of possible failure in the future.
2:16-CV02191-PHX-DGC	Brown, Linda	Curtis		
2:16-CV02193-PHX-DGC	Allemand, Nancy	Curtis	Bard G2	Tilt with filter embedded in wall of the IVC / device unable to be retrieved Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to; mental anguish, pain and suffering.
2:16-CV02194-PHX-DGC	Fletcher, Hilda	Curtis	Bard G2	Shortness of breath, heart palpitations, exhaustion Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, difficulty breathing, palpitations, lightheadedness, neck pain, weakness nausea and fear of possible failure in the future.
2:16-CV02195-PHX-DGC	Will, Nancy	Johnson		
2:16-CV02196-PHX-DGC	D'Antonio, Michael	Curtis	Bard Denali	Device unable to be retrieved / Other failure mode(s) Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to; I feel like a "ticking time

				bomb” because of the possibility of a failure in the future. I am stressed and suffer from mental anguish and pain.
2:16-CV02197-PHX-DGC	Hunt, Carl	Curtis	Bard Meridian	Device unable to be retrieved Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants’ IVC filter. Plaintiff’s symptoms and injuries include, but are not limited to, have had an increase in blood clots that have formed above and below the filter, and the filter is now irretrievable, this has made walking and movement very painful and debilitating.
2:16-CV02198-PHX-DGC	Layman, Janet Fay	Johnson		
2:16-CV02199-PHX-DGC	Hoover, Carla	Curtis	Bard G2	Fracture/ The filter was tilted and fractured Plaintiff refers defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants’ IVC filter. Plaintiff’s symptoms and injuries include but are not limited to, lower back pain and numbness of legs, and fear that the part of the filter left inside of me could migrate and or cause more severe injuries in the future, even death.
2:16-CV02200-PHX-DGC	Bois, Kyle	Johnson		
2:16-CV02205-PHX-DGC	Licea, Luz	Gaddy		
2:16-CV02210-PHX-DGC	Phares, Barry	Buttars	G2	Severe and persistent chest pain, shortness of breath, and

				<p>recurrent pulmonary embolism</p> <p>Severe and persistent chest pain, shortness of breath and recurrent pulmonary embolism</p>
2:16-CV02216-PHX-DGC	Zackowski, Maria	Nolen		
2:16-CV02217-PHX-DGC	Gibbs, Victoria	Nolen		
2:16-CV02218-PHX-DGC	Lowman, Donna Lee Lowman, Gary	Johnson		
2:16-CV02219-PHX-DGC	Andalon, Arthur Sr. Andalon, Yvette	Johnson		
2:16-CV02220-PHX-DGC	Gates, Christian Leigh	Johnson		
2:16-CV02221-PHX-DGC	Janes, Debora	Johnson		
2:16-CV02222-PHX-DGC	Brown, Tracy Lawrence	Johnson		
2:16-CV02223-PHX-DGC	Fields, Teresa	Johnson		
2:16-CV02224-PHX-DGC	Bell, Frank Bell, Marietta	Johnson		
2:16-CV02231-PHX-DGC	Chargois, Brandi	Bertram		
2:16-CV02234-PHX-DGC	Powell, Kevin Michael	Trost	Recovery	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV02236-PHX-DGC	Niemeyer, Brent Niemeyer, Keely	Kulesza	Recovery	<p>Fracture / Perforation of filter strut(s) into organs / Tilt with filter embedded in wall of the IVC/ Device unable to be retrieved/</p> <p>If other, please describe: Four legs of the filter broke off and migrated to various parts of my body – left pleural space, right subsegmental pulmonary artery, left abdominal small bowel mesentery, and extravascular</p>

				<p>retroperitoneum. Not all of the pieces can be surgically removed.</p> <p>I had to survive surgery in the middle of my education and I had to deal with years of chest pain until discovering the filter strut in my ribs. I then dealt with the psychological stress of the IVC filter breaking apart and harming my body. I had to reduce my level of exercise due to the risk of the fractured strut in my intestines, which led to weight gain. Surgery to remove the filter brought on neck pain and more stress at the thought of leaving other fractured pieces in dangerous parts of my body. I now have to be on blood thinning medication for the rest of my life and I have to have annual x-rays to monitor the movement of any remaining filter struts.</p> <p>My life has drastically changed for the worse, as I now constantly worry for my health and safety. The multiple surgeries have been hard on my body and I fear they will never end. The filter has caused numerous problems with my health. I am constantly stressed and scared.</p> <p>Whenever I have pain I immediately think that a fractured strut of the filter has</p>
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				<p>caused a problem. I have to see doctors regularly, which makes me miss important family and life events because I am either in pain, recovering from surgery, stressed about causing a fractured strut to puncture vital organs, or fearing that something else will go wrong. I am glad the filter was partially removed but I am now worried about the struts that cannot be removed and their location. I am worried about a lifetime of x-ray monitoring to make sure the fractured struts do not move and I am upset about a lifetime of Coumadin medication. I hurt for years until the fractured strut in my chest was first discovered, then I hurt for a year until the filter was removed. Now more fractured struts of the filter have been discovered and my life has changed.</p> <p>I cannot go back to boot camp exercise until the fractured strut is removed from my intestines.</p> <p>My academic professor refers to me as a liability and I have had to alter my education practice because of the fractured filter that was supposed to save my life and make things easier. I am frustrated and bewildered that</p>
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				one device can do, and has done, so much harm.
2:16-CV02237-PHX-DGC	Basile, Vincent	Dudley	G2	Perforation of filter strut(s) into organs, tilt with filter embedded in wall of the IVC, device unable to be retrieved
2:16-CV02238-PHX-DGC	Scott, Everett Scott, Kathryn	Johnson		
2:16-CV02239-PHX-DGC	Radke, Diane Radke, George	Johnson		
2:16-CV02241-PHX-DGC	Houck, Margaret Houck, Robert Thomas	Johnson		
2:16-CV02242-PHX-DGC	McPeak, Kathleen	Skrabanek	G2	Ultrasound reported migration and protrusion through the blood vessel
2:16-CV02243-PHX-DGC	Bushman, Alan Bushman, Stacy	Johnson		
2:16-CV02244-PHX-DGC	Corba, Barbarea Corba, Joel Thomas	Johnson		
2:16-CV02245-PHX-DGC	Bright, Richard	Johnson		
2:16-CV02252-PHX-DGC	Douglas, Athena	Johnson		
2:16-CV02254-PHX-DGC	Gonzalez, Jeanette Gonzalez, William	Johnson		
2:16-CV02255-PHX-DGC	Chance, Cassidae Amber Chance, Matt	Johnson		
2:16-CV02256-PHX-DGC	Foreman, Ronnice Foreman, Stanley	Johnson		
2:16-CV02257-PHX-DGC	George, Christopher George, Rachel	Smith	Recovery	Fracture / Perforation of filter strut(s) into organs / Migration of struts to heart and to the abdomen Depression, chronic pain in the abdomen, continued blood clots, and suffered a stroke from IVC removal, among other complications

2:16-CV02258-PHX-DGC	Lindow, Christopher	Fiebiger, Johnson, Pearson	G2® Vena Cava	<p>Filter became occluded, obstructing blood flow and causing veins to bulge. This led to lipodermatosclerosis and DVTs in both legs. Client must now take blood thinners for the rest of his life to compensate for damage to veins.</p> <p>Plaintiff has experienced multiple ongoing medical issues as a result of the Bard IVC Filter, including but not limited to bulging veins, poor leg circulation, extreme swelling of right leg lipodermatosclerosis, and DVT's. Plaintiff also has to take blood thinners for the rest of his life with monthly blood tests, and has to be extremely careful not to bump right leg or skin will break open and it will take months to heal.</p>
2:16-CV02265-PHX-DGC	Hash, Jonathan Hash, Tammy	Johnson		
2:16-CV02266-PHX-DGC	Perry, Diane <i>Deceased party's spouse</i>	Michael T. Gallagher		
2:16-CV02267-PHX-DGC	Taylor, John Sr. Taylor, Roberta	Michael T. Gallagher		
2:16-CV02272-PHX-DGC	Evans, Sandra	Liebhard	Eclipse	<p>Tilt with filter embedded in wall of the IVC</p> <p>I sustained significant injuries due to the C.R. Bard IVC Filter including, but not limited to, inability to have the IVC filter removed</p>
2:16-CV02273-PHX-DGC	Helton, Harlan	Michael T. Gallagher		
2:16-CV02274-PHX-DGC	Frailich, Alan Frailich, Yvonne	Michael T. Gallagher		
2:16-CV02275-PHX-DGC	Dalbotten, Maria	Scarpelli	G2® Vena Cava filter	Fracture / Perforation of filter strut(s) into organs / Bleeding

				I have continuing pain at the site of the incision done on May 20, 2016 to remove the fragment from my heart. Also, I am suffering from depression and post-traumatic stress disorder for which I am receiving treatment
2:16-CV02278-PHX-DGC	Young, Carolyn	Bertram		
2:16-CV02279-PHX-DGC	Smetak, Jerry James	Bertram		
2:16-CV02280-PHX-DGC	Lewis, Michael	Bertram		
2:16-CV02281-PHX-DGC	Auzenne, Sandra	Bertram		
2:16-CV02293-PHX-DGC	Guzman, Benny	Osborne	Meridian	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved Mental and physical fatigue; headaches; soreness and pain; mental anguish and anxiety due to filter still being implanted
2:16-CV02296-PHX-DGC	Midkiff, Tricia Ann	Nations	Recovery	Fracture / Stress, anxiety, shortness of breath, breathing trouble, coughing, chest pain
2:16-CV02297-PHX-DGC	Ross, Rachel Marie	Potts	Meridian	Perforation of filter strut(s) into organs/ Device unable to be retrieved / Tilt with filter embedded in wall of the IVC. Plaintiff has suffered from perforation of two struts through the lateral wall of the IVC into the medial right renal cortex and posterior wall of the descending duodenum, tilting of the filter from its original position, embedding of the filter into the IVC wall making it irretrievable, pain and suffering, and other injuries as they become apparent.
2:16-CV02300-	Flood, Matthew	Lopez	Eclipse	Perforation of filter strut(s)

PHX-DGC				<p>into organs / Perforation of the vena cava and abdominal aorta</p> <p>Plaintiff refers Defendants to his medical records for complete details of the injuries he has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, emotional and physical pain and suffering. Specifically, Plaintiff developed abdominal and chest pain and it was discovered on CT scan that multiple struts of the filter were perforating the vena cava and surrounding to aorta, possibly perforating the aorta. Given this finding, the filter was removed percutaneously on May 20, 2011, at which time it was confirmed that three tines were touching the aorta.</p>
2:16-CV02304-PHX-DGC	Webster, Dewitt	Fishback Riley	Denali	<p>Plaintiff is experiencing chest pain, sharp pain in lower extremities and toes and occasionally in head. Plaintiff is also experiencing episodes of vertigo. Plaintiff is also experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extents of plaintiff's injuries are unknown at this time as they continue to develop.</p>
2:16-CV02318-PHX-DGC	Dulong, Joseph Dulong, Roseanne	Nations	Eclipse	<p>Perforation of vena cava wall Stress, anxiety</p>
2:16-CV02340-PHX-DGC	Coleman, Esther	Johnson		

2:16-CV02341-PHX-DGC	Huff, Julia Ann Huff, Othel Dayle	Johnson		
2:16-CV02342-PHX-DGC	Ostap, Jerry Ostap, Nadine	Johnson		
2:16-CV02343-PHX-DGC	Dutton, Michael Dutton, Teresa	Johnson		
2:16-CV02344-PHX-DGC	Enriquez, Deborah	Johnson		
2:16-CV02345-PHX-DGC	Falls, Clifford Falls, Nancy	Johnson		
2:16-CV02346-PHX-DGC	Walker, Linda	Johnson		
2:16-CV02350-PHX-DGC	Jimenez, Paulette	Decker Fleishman		
2:16-CV02353-PHX-DGC	Hill, Diann Hill, John Jr.	Osborne	Recovery	Fracture / Migration for at least 1 cm. Worried that filter may travel to heart or lungs.
2:16-CV02354-PHX-DGC	Walker, Dolores	Osborne	G2	Filter placed after being diagnosed with deep vein thrombosis/pulmonary embolism. History of clots in both lungs and I was having both knees replaced
2:16-CV02359-PHX-DGC	Putnel, Dana	Hammers		
2:16-CV02362-PHX-DGC	Martin, Patricia	Trebisacci		
2:16-CV02374-PHX-DGC	Bower, John	Bertram		
2:16-CV02382-PHX-DGC	Tunstall, Roderick	Johnson		
2:16-CV02383-PHX-DGC	Gray, Roy Medina, Yolanda	Johnson	Meridian (Medina)	Severe pain in implant area and chest pain. Also poking feeling in upper side areas. Mental anguish, anxiety that the filter has failed or will fail and cause additional medical problems. (Medina)
2:16-CV02384-PHX-DGC	Carroll, Dwayne	Johnson		
2:16-CV02393-PHX-DGC	Beason, Betty	Lopez	Meridian	Fracture / Embolization of fractured strut to the lung; and two retained fractured struts, within the wall of the inferior

				<p>vena cava and in the lung</p> <p>Plaintiff refers Defendants to her medical records for complete details of the injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to. Emotional and physical pain and suffering. Specifically, Plaintiff presented for planned retrieval of the filter, as it was only intended as a temporary device, at which time it was discovered to have fractured. One of the struts was found to be embedded within the wall of the inferior vena cava and another had migrated into the left lung. The struts were left in place and remain implanted.</p>
2:16-CV02402-PHX-DGC	Morris, Julie	Morris		
2:16-CV02417-PHX-DGC	Cox, Brenda Ledbetter	Johnson		
2:16-CV02428-PHX-DGC	Browning, Barry Lee	Dudley	Denali	<p>Post IVC implantation began having shortness of breath, feeling like I was smothering, and tingling to my jaw and neck. Dr. Sartawi told me that these could be side effects of the IVC filter and recommended it be removed. Dr. Sartawi told me that he could not remove it through my groin and would have to try to get it out through my neck</p>
2:16-CV02429-PHX-DGC	Eaton, Mary Ann	Dudley	Recovery	Unknown until CT scan performed to evaluate the filter
2:16-CV02442-PHX-DGC	Brown, Steven	Driscoll	Denali	Tilt with filter embedded in wall of the IVC.

2:16-CV02443-PHX-DGC	Pastor, Amparo	Shultz		
2:16-CV02444-PHX-DGC	Snype-Stewart, Vivica	Goldenberg	Denali	Plaintiff now requires constant medical monitoring. Plaintiff lives with the daily fear that the filter may malfunction, knowing that if it does, little can likely be done
2:16-CV02445-PHX-DGC	Williams, Gwendolyn	Goldenberg	Denali	Plaintiff requires frequent medical monitoring. Plaintiff lives with the daily fear that the filter may malfunctions, knowing that if it does, little can likely be done.
2:16-CV02450-PHX-DGC	Baskom, Lakeya	Johnson		
2:16-CV02451-PHX-DGC	Gualdoni, Linda	Johnson		
2:16-CV02452-PHX-DGC	Trotman, Jessie Trotman, Contessa	Johnson		
2:16-CV02454-PHX-DGC	Scott, Mary Lynn	Johnson		
2:16-CV02465-PHX-DGC	Coffman, Elizabeth	Osborne		
2:16-CV02466-PHX-DGC	Jones, Greta	Osborne		
2:16-CV02467-PHX-DGC	Wood, Rozella	Osborne	Bard G2	Tilt with filter embedded in wall of the IVC/ Device unable to be retrieved My symptoms are fear and emotional distress of my G-2 IVC filter breaking or fracturing into my heart or lungs.
2:16-CV02468-PHX-DGC	Richards, Karen Richards, Robert	Lopez	G2	Perforation of filter strut(s) into organs / Device unable to be retrieved / Perforation of inferior vena cava and aorta; retained filter, requiring regular monitoring and lifelong anticoagulation Plaintiff refers Defendants to

				<p>his medical records for complete details of the injuries he has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to, emotional and physical pain and suffering. Specifically, it was discovered on a CT scan that at least one filter prong was extending outside lumen of the cava. He saw two vascular surgeons, who evaluated the scan and relayed that the filter had grown into the aorta and could not be removed without causing rupture and / or death. After suffering a stroke on October 19, 2010, Plaintiff was placed on lifelong anticoagulation. The filter remains implanted and Plaintiff has been instructed to undergo annual imaging to monitor it.</p>
2:16-CV02475-PHX-DGC	Jones-Hancock, Mary	Johnson		
2:16-CV02476-PHX-DGC	Thornburg, Robert Thornburg, Sheryl	Johnson		
2:16-CV02477-PHX-DGC	Clinton, Willia Mae	Johnson		
2:16-CV02478-PHX-DGC	Rivera, Carmen	LippSmith	G2	<p>Device unable to be retrieved Ineffective filter; irretrievable filter; unsuccessful surgical intervention; fear of further complications such as migration and/or fracture of the filter; and fear of untimely death due to the filter.</p>
2:16-CV02482-PHX-DGC	Cook, Ronald Cook, Stephanie	Lopez		
2:16-CV02485-	Wilson, Tina	Johnson		

PHX-DGC				
2:16-CV02495-PHX-DGC	Rankin, Allan Rankin, Sallie	Clinton	Bard recovery	Perforation of filter strut(s) into organs / Tilt with filter embedded in wall of the IVC / Device unable to be retrieved
2:16-CV02496-PHX-DGC	Madison, Charles Edward	Bossier		
2:16-CV02497-PHX-DGC	Newcomb, Leroy Newcomb, Patricia	Clinton		
2:16-CV02498-PHX-DGC	Marshall, Jeffrey Marshall, Susan	Clinton	Bard Recovery	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved / Bleeding
2:16-CV02499-PHX-DGC	Crutchfield, Hank	Bossier		
2:16-CV02500-PHX-DGC	Aldridge, Aron	Bossier		
2:16-CV02501-PHX-DGC	Christoffer, Barbara	Bossier		
2:16-CV02506-PHX-DGC	James, Nancy	Schultz		
2:16-CV02515-PHX-DGC	Eisenbrandt, Susan	Johnson		
2:16-CV02516-PHX-DGC	Exley, Esther <i>As representative</i>	Bossier Matthews		
2:16-CV02517-PHX-DGC	Custer, Susan	Bossier Matthews		
2:16-CV02525-PHX-DGC	Sloan, Shelia	Blizzard		
2:16-CV02531-PHX-DGC	Riley, Tenisha	Bossier Matthews		
2:16-CV02532-PHX-DGC	Rogers, Michael	Bossier Matthews		
2:16-CV02539-PHX-DGC	Lord, Sandra	Fishback Riley	Bard Denali	Plaintiff is experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extents of plaintiff's injuries are unknown at this time as they continue to develop.
2:16-CV02540-	Fox, Jill Allison	Fishback	Bard G2	Plaintiff is experiencing

PHX-DGC		Riley		<p>mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop</p> <p>Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendants' IVC filter. Plaintiff's symptoms and injuries include, but are not limited to: Plaintiff is experiencing mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop.</p>
2:16-CV02541-PHX-DGC	Dozier, Sara	Fishback Riley	Bard Denali	<p>Plaintiff is experiencing chest pain, back pain, numbness in right shoulder and shortness of breath. Plaintiff is also experiencing panic attacks and lack of sleep and mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extent of plaintiff's injuries are unknown as they continue to develop.</p> <p>Plaintiff refers Defendants to her medical records for complete details of her injuries she has suffered stemming from Defendant's IVC filter. Plaintiff's</p>

				symptoms include but are not limited to: Plaintiff is experiencing chest pain, back pain, numbness in right shoulder and shortness of breath. Plaintiff is also experiencing panic attacks and lack of sleep and mental anguish and anxiety that the filter has failed or will fail causing additional medical problems. The remaining extent of plaintiff's injuries are unknown at this time as they continue to develop.
2:16-CV02546-PHX-DGC	Webb, James Webb, Roxanna	Goldenberg	Eclipse	Plaintiff now requires frequent medical monitoring. Plaintiff lives with the daily fear that the filter may malfunction, knowing that if it does, little can likely be done.
2:16-CV02549-PHX-DGC	Cecchine, Patsy	Hoerman		
2:16-CV02552-PHX-DGC	Pfenning, Paul	Nations		
2:16-CV02558-PHX-DGC	Casey, Annette Casey, Gordon	Seldomridge	Eclipse	Perforation of filter strut(s) into organs / Tilt with filter embedded in wall of the IVC / Device unable to be retrieved I have factor II mutation which encourages small clots to be formed and passed to my heart and a VSD which allows the clots to go to my brain. I have had DVT and PVD and want the filter removed, but the surgery is too risky. Films from a4/16/13 scan show filter arms in aorta layer
2:16-CV02559-PHX-DGC	Person, Michael	Cartmell		
2:16-CV02561-PHX-DGC	Sargeant, Elaine Sargeant, Gary	Bogdan		

2:16-CV02565-PHX-DGC	Thurman, Shirley	Bossier Matthews		
2:16-CV02566-PHX-DGC	Seals, Evelyn	Bossier Matthews		
2:16-CV02568-PHX-DGC	Oakleaf, Carol Oakleaf, Kenneth	Johnson		
2:16-CV02569-PHX-DGC	Cordes, Heidi Cordes, Henry	Johnson		
2:16-CV02570-PHX-DGC	Leigh, James	Lopez		
2:16-CV02571-PHX-DGC	Kuhn, John Kuhn, Marianna	Johnson		
2:16-CV02572-PHX-DGC	Street, Harold Street, Sandra	Johnson		
2:16-CV02576-PHX-DGC	Scholer, Joseph	Dudley		
2:16-CV02580-PHX-DGC	White, Irene Moore	Nations		
2:16-CV02582-PHX-DGC	Komorowski, Richard	Lopez		
2:16-CV02583-PHX-DGC	Galan, Robert	Bossier		
2:16-CV02586-PHX-DGC	Thompson, James <i>Obo Sharon R. Thompson</i>	Bossier Matthews		
2:16-CV02589-PHX-DGC	Hare, Betty	Allen Williams		
2:16-CV02601-PHX-DGC	Moore, Daniel Moore, Donna	Leh		
2:16-CV02603-PHX-DGC	Bazan, Eulalio	Decker, Fleishman, Seltz		
2:16-CV02604-PHX-DGC	Winterbottom, Doris Winterbottom, John III	Johnson		
2:16-CV02605-PHX-DGC	Worsley, Patricia Worsley, Richard	Johnson		
2:16-CV02606-PHX-DGC	Martinez, Luisa Ivanna	Johnson		
2:16-CV02619-PHX-DGC	Ward, Marie E	Beard Lewis		
2:16-CV02620-PHX-DGC	Briggs, Donna	Flaherty		
2:16-CV02621-PHX-DGC	Matthews, April Christine	Bentley Zonies		

2:16-CV02622-PHX-DGC	Miramontez, David Jr.	Nations		
2:16-CV02623-PHX-DGC	Elliott, Donald	Davick Johnston		
2:16-CV02625-PHX-DGC	Newsom, Carlos	Lopez		
2:16-CV02626-PHX-DGC	Dyer, Dona Jane	Decker Fleishman		
2:16-CV02627-PHX-DGC	Peterson, Laura Peterson, Trevor	Decker Fleishman		
2:16-CV02628-PHX-DGC	Sheppard, Richard	Decker Fleishman		
2:16-CV02634-PHX-DGC	Rowntree, Lauren as Proposed Conservator of Zachary MacDonald	Bogdan		
2:16-CV02651-PHX-DGC	Brown, Ralph	Barreca		
2:16-CV02655-PHX-DGC	Natola, Trent and Leatrice	Barreca		
2:16-CV02656-PHX-DGC	Mattucci, Gail	Barreca		
2:16-CV02657-PHX-DGC	Matthews, Kenneth and April	Barreca		
2:16-CV02664-PHX-DGC	Dorough, Allen R.	Van Der Veer		
2:16-CV02665-PHX-DGC	Crepeau, John D.	Van Der Veer		
2:16-CV02666-PHX-DGC	Jenkins, David and Karin	Barreca		
2:16-CV02667-PHX-DGC	Carney, Tara and Keith	Barreca		
2:16-CV02668-PHX-DGC	LaBurt, Maureen	Barreca		
2:16-CV2680-PHX-DGC	Goforth, Sherri and William as attorney-in-fact for Katie Goforth (deceased)	Seltz		
2:16-CV 2683-PHX-DGC	Sulligan, Frank George and Deborah Elaine	Nations		
2:16-CV 2684-	Garcia, Sharon	Winegar		

PHX-DGC		Kidd Perdue		
2:16-CV 2689- PHX-DGC	Pierce, Tharanika on behalf of Thaddeus Pierce	Barnes McCarthy Alvarez	Meridian	Pulmonary Embolism suffered – post-placement of Meridian IVC Filter Pulmonary embolism on January 15, 2015 post Filter placement; Death on October 25, 2015
2:16-CV 2693- PHX-DGC	Harrell, Youlanda	Kincannon Cowper		
2:16-CV 2694- PHX-DGC	Leslie, Stephen and Debbie	Kincannon Cowper		
2:16-CV 2700- PHX-DGC	Farrington, Donna Marie	Goss		
2:16-CV 2701- PHX-DGC	Clark, James Norwood, Jr. and Ann Clark	Johnson		
2:16-CV 2702- PHX-DGC	Brown, Cougar M.	Johnson		
2:16-CV 2704- PHX-DGC	Holder, Teresa R.	Nolen		
2:16-CV 2710- PHX-DGC	Todd, Richard A.	Lopez		
2:16-CV 2714- PHX-DGC	Guinn, April	DeGaris		
2:16-CV 2716- PHX-DGC	Sneed, Lisa	DeGaris		
2:16-CV 2729- PHX-DGC	Rodriguez, Rodney Jay	McCarthy Horovitz Hedrick		
2:16-CV 2730- PHX-DGC	Bethany, Karen G.	Jackson Bossier		
2:16-CV 2731- PHX-DGC	Martin, Debra	Schultz		
2:16-CV 2735- PHX-DGC	Kanipe, Mary S. and James	Hodge King		
2:16-CV 2738- PHX-DGC	Ekblad, Gail & Guy	Lopez		
2:16-CV 2746- PHX-DGC	Watson, William – Estate of Ann Marie Watson	Lopez		
2:16-CV 2747- PHX-DGC	Houston, Amy Jean	Nations		
2:16-CV 2749-	Fahnestock,	Fitzgerald		

PHX-DGC	Deborah			
2:16-CV 2751-PHX-DGC	Spencer, Pamela	Seeger		
2:16-CV 2752-PHX-DGC	Treinaicvz, Kathryn	Seeger		
2:16-CV 2753-PHX-DGC	Watson, Samuel	Seeger		
2:16-CV 2766-PHX-DGC	Ameel, Alexis A.	Matthews Bossier		
2:16-CV 2769-PHX-DGC	Ennis, Alan	Mason Lane Schulte		
2:16-CV 2772-PHX-DGC	Veltkamp, John and Iris Beth	Lopez		
2:16-CV 2783-PHX-DGC	Petersen, Margaret & Randy	Johnson		
2:16-CV 2785-PHX-DGC	Edwards, Monica	Johnson		
2:16-CV 2791-PHX-DGC	Boyd, Juliette	Martin		
2:16-CV 2798-PHX-DGC	Bizzarro-Pierro, Anne & Robert	Plotkin		
2:16-CV 2799-PHX-DGC	Orgad, Stephanie	Plotkin		
2:16-CV 2822-PHX-DGC	Godfrey, Lori	Lopez		
2:16-CV 2824-PHX-DGC	Townsend, Nancy	Seeger		
2:16-CV 2827-PHX-DGC	Johnson, Wanda	Goss		
2:16-CV 2833-PHX-DGC	Gibson, Charles	Lopez		
2:16-CV 2834-PHX-DGC	Cuttler, Alvin & Henrietta	Van Der Veer		
2:16-CV 2836-PHX-DGC	Burner, Neason	Osborne		
2:16-CV 2839-PHX-DGC	Gause, James Leroy	Nations		
2:16-CV 2841-PHX-DGC	Kelly, Yolanda	Nations		
2:16-CV 2850-PHX-DGC	Bush, Arthur	Wendt		
2:16-CV 2853-PHX-DGC	Novy, Angela Becker, Frederick	Grebel Niemeyer Kruse		

	Collins, Larry Palmer, Wilson Williams, Juanita Beste, Sarah Powers, Heather Crowley, Laura Elwell, Terry Grossman, Joseph Maxfield, James Bilal, Abdul- Mutaal Kotter, Allan Gill, Denise Hinchman, Faith Baggett, Michelle Gibson, Angela Reynoldson, Diane Cardonna, Joann Smith, Jason Dykema, Tammy Walker, Tony May, Sheila Morrison, Brian Holms, III, Melvin Robinson, Eric Baker, Christine Houston, Cynthia Kennedy, Tina McGrath, Peter Saad, Sabir Smith, Ronell Vegiard, Wilfred Weiss, Jerome Adams, Alana Artist-Rogers, Helen Brown, Sr., William Carroll, Jessica L. Collins, Suetie Nicol, James			
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	Marshall, Vanessa Salters, William Simerly, Jerry Thomas, Annie			
2:16-CV 2858- PHX-DGC	Wright-Butler, Cheryl	Murphy Comeaux	G2	Tilt with filter embedded in wall of the IVC / Device unable to be retrieved I am taking Warfarin since 2009. I was told I have to take it for LIFE since blood clots can form around the unremoved filter. Taking Warfarin is a hardship to me. I have to monitor everything I do and eat because of the blood thinner. I have to go to the Lab monthly for INR testing.
2:16-CV 2862- PHX-DGC	Waggoner- Roberts, Lisa	Hogins Moody		
2:16-CV 2865- PHX-DGC	Shields, Larry	Curtis		
2:16-CV 2875- PHX-DGC	Brummett, Billy Gene	Queener		
2:16-CV 2877- PHX-DGC	Banton, Patricia	Kahana Hatch		
2:16-CV 2883- PHX-DGC	Spears, Carol Mary & Dale	Nations		
2:16-CV 2901- PHX-DGC	Christensen, Tobie Raychelle Whipple	Bradley, Jr.		
2:16-CV 2913- PHX-DGC	Lugo, Irene	Kahana Hatch		
2:16-CV 2919- PHX-DGC	Robbins, Alvin & Sally	Goss		
2:16-CV 2920- PHX-DGC	Russell, Sarah Jane	Nations		
2:16-CV 2922- PHX-DGC	Rotondo, Carol Ann	Nations		
2:16-CV 2931- PHX-DGC	Arrington, Daniel	Wendt		
2:16-CV 2932- PHX-DGC	Naifeh, Sam	Wendt		
2:16-CV 2940- PHX-DGC	Jurns, Bethany & David	Clinton		

2:16-CV 2944-PHX-DGC	Parsons, Rosalie	DeGreeff Cartmell		
2:16-CV 2945-PHX-DGC	DeHart, Robert	DeGreef Cartmell		
2:16-CV 2952-PHX-DGC	Terrasas, Roland	Mendenhall Freese Matthews		
2:16-CV 2953-PHX-DGC	Kolpakowski, Marie O.	Mendenhall Freese Matthews		
2:16-CV 2954-PHX-DGC	Cameron, Nathaniel	M. Skikos Mielke S. Skikos		
2:16-CV 2955-PHX-DGC	Collins, Brenda	Wendt		
2:16-CV 2971-PHX-DGC	Barnes, Ida Mae	Seltz Decker Fleishman		
2:16-CV 2977-PHX-DGC	Williams, Jessica	Martin		
2:16-CV 2985-PHX-DGC	Wittenbert, Abigail	Lopez		
2:16-CV 2989-PHX-DGC	Halle, Deborah and Roland	Tuttle		
2:16-CV 2991-PHX-DGC	Marengo, Rosemarie	Bailey		
2:16-CV 2998-PHX-DGC	Porn, Daryl	Mendenhall Matthews Freese		
2:16-CV 2999-PHX-DGC	Kelly, Daniel and Mary	Nations		
2:16-CV 3008-PHX-DGC	Fey, Godfrey, Jr. and Linda	Bond		
2:16-CV 3015-PHX-DGC	Hammond, Lorella	McEwen		
2:16-CV 3022-PHX-DGC	Jiles, Gayola	Nations		
2:16-CV 3024-PHX-DGC	Paine, Jared	Lopez		
2:16-CV 3033-PHX-DGC	Hunt, Ocie Lee and Gladys Marie Hunt	Seltz Decker Fleishman		
2:16-CV 3043-PHX-DGC	Myrie, Melford C.	Johnson		
2:16-CV 3044-PHX-DGC	Narayan, Ashwin and Roefi	Johnson	Eclipse	Tilt with filter embedded in wall of the IVC, Device

				unable to be retrieved Depression, loss of job (Discharged from the air force), Mental anguish
2:16-CV 3045- PHX-DGC	Zalite, Deborah	Johnson		
2:16-CV 3046- PHX-DGC	Bryant, Debra	Williams Allen		
2:16-CV 3047- PHX-DGC	Gray, Randy and Deanne	Johnson		
2:16-CV 3048- PHX-DGC	Wiggins, Weldon	Johnson		
2:16-CV 3070- PHX-DGC	Wray, Janice	Stackhouse Schultz		
2:16-CV 3071- PHX-DGC	Pinegar, Timothy	Pinegar (pro se)		
2:16-CV 3076- PHX-DGC	Gandel, Sandra G.	Groher		
2:16-CV 3077- PHX-DGC	Milam, Melissa M.	Nolen		
2:16-CV 3081- PHX-DGC	Schmid, Matthew Edward	Nations		
2:16-CV 3082- PHX-DGC	Nelson, Steve Gary	Nations		
2:16-CV 3088- PHX-DGC	Shea, Eileen	Stackhouse		
2:16-CV 3089- PHX-DGC	Kopoulos, Alexandro	Dudley		
2:16-CV 3093- PHX-DGC	Branham, Joseph Donald	Nations		
2:16-CV 03121- PHX DGC	Gray, Edna M.	Murphy	Eclipse	PE with filter in place, depression, anger, anxiety, stomach pain, shortness of breath
2:16-cv-02242	Gurries, Jamey	Driscoll	Eclipse	Device unable to be retrieved. Anxiety, trouble breathing and sleeping, head tingling.
2:16-cv-02242	Williams, Betty	Driscoll	G2	Device unable to be retrieved
2:16-cv-02242	Ross, Katrina	Driscoll	G2	Tilt with filter embedded in wall of the IVC.
2:16-cv-02242	Martinez, Nancy	Driscoll	Denali	Blood clot in lung after hernia surgery May 2015.
2:16-cv-02242	Lohr, Beverly	Driscoll	G2 Express	Tilt with filter embedded in wall of the IVC.

2:16-cv-02242	Iglewski, Rudolph	Driscoll	G2	Device unable to be retrieved
2:16-cv-02242	Gurries, Jamey	Driscoll	Eclipse	Device unable to be retrieved
2:16-cv-02242	Brown, Steven	Driscoll	Denali	Tilt with filter embedded in wall of the IVC.
2:16-cv-03122-DGC	Murray, John	Murphy	G2	Large clot was lodged in the IVC filter with a small amount of it partially protruding through the filter. Another IVC had to be placed.

Schedule 2 – History and Chronology of Vena Cava Filters

Schedule 2 – History and Chronology of IVC Filters

Date	Event
Mid-1950s	Various devices proposed for temporary or partial interruption of the IVC. This included temporary exclusion of the VIC with removable metal or plastic clips, temporary ligation of the IVC with absorbable catgut, and plication or compartmentalization of the IVC with a mechanical stapler, dividing it into multiple small channels. ¹ These devices did not provide a substantial improvement to the fatality rate. ²
1958	Marion S. DeWeese constructed the first intraluminal “harp grip” filter, which could block the transit of emboli without significantly disturbing the function or dynamics of the venous system. This was done by placing mattress stitches of silk sutures across the infrarenal vena cava. ³ This device showed promising results in preventing PE, but its placement still required major surgery and general anesthesia. ⁴
1967	This problem was solved with the Mobin-Uddin umbrella filter, which was created in 1967. ⁵ The Mobin-Uddin filter could be installed with a catheter under local, rather than general, anesthesia. ⁶ The initial prototype of the Mobin-Uddin umbrella filter was

¹ J.P. Galanaud, J.P. Laroche, and M. Righini, The history and historical treatments of deep vein thrombosis, 10 J of Thrombosis and Haemostasis 402, 407 (2013).

² F.G. Barral, Vena cava filters: why, when, what and how?, 49 J Cardiovasc Surg 35, 35-36 (2008).

³ Patrick G. Cain, MD, *Comment on “Treatment of venous disease – the innovators”*, 22 J Vasc Surg 341, 341-42 (1995).

⁴ J.P. Galanaud, J.P. Laroche, and M. Mighini, *The history and historical treatments of deep vein thrombosis*, 10 J of Thrombosis and Haemostasis 402, 407 (2013).

⁵ A vena caval filter for the prevention of pulmonary embolus, Mobin-Uddin K, Smith PE, Martinez LO, Lombardo CR, Jude JR, Surg Forum, 1967.

⁶ *Id.*

	made by Mr. Robert McLean at the Department of Medical Instrumentation at the University Of Miami School Of Medicine. The spokes of the filter were made of elgiloy and were covered with a thin sheet of Silastic that had 3 mm perforations.
1970	After experimental evaluation and clinical trials, the Mobin-Uddin umbrella filter was released for general clinical use in 1970. ⁷
Early 1970s	One of the main problems with the initial design of the Mobin-Uddin filter was the gradual obstruction of the IVC. ⁸ This was partially prevented by coating the device with heparin to allow the blood to flow easier. ⁹ The heparin-bonded Mobin-Uddin umbrella filters remained patent when implanted in the vena cava. ¹⁰
1973	Greenfield develops the first vena cava “filter.” But this filter needed venotomy because of its external calibre. ¹¹
1981	Greenfield develops the first true percutaneous filter, which did not necessitate any venotomy. ¹² This was followed by a rapid increase in the indications for and the number of implantations of IVC filters. ¹³ There was also an explosion of the number of filters available on the market. ¹⁴ This increase in the number of reflects, on the one hand, the difficulties met by industrialists in designing the ideal filter and, on the other hand, the crucial lack of elements in the literature allowing to conform the efficacy of these devices in the treatment of the venous thromboembolism disease. ¹⁵
1990s	Non-permanent vena cava filters were not available for on-label use in the United States until over 30 years after the Mobin-Uddin filter was created in 1967, when the instructions for use of three existing permanent filters were changed to allow percutaneous retrieval. ¹⁶
1992	Bard begins distributing the Simon Nitinol Filter for Nitinol Medical Technologies

⁷ Patrick G. Cain, MD, *Comment on “Treatment of venous disease – the innovators”*, 22 J Vasc Surg 341, 341-42 (1995).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ F.G. Barral, *Vena cava filters: why, when, what and how?*, 49 J Cardiovasc Surg 35, 35-36 (2008).

¹² Greenfield LJ, *Historical Reminiscence: Origin of the Greenfield Filter*, 76 Am Surg 1319, 1319-20 (2010).

¹³ F.G. Barral, *Vena cava filters: why, when, what and how?*, 49 J Cardiovasc Surg 35, 36 (2008).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ John A. Kaufman, *Optional Vena Cava Filters: What Why and When*, 15 Vascular 304, 304 (2007).

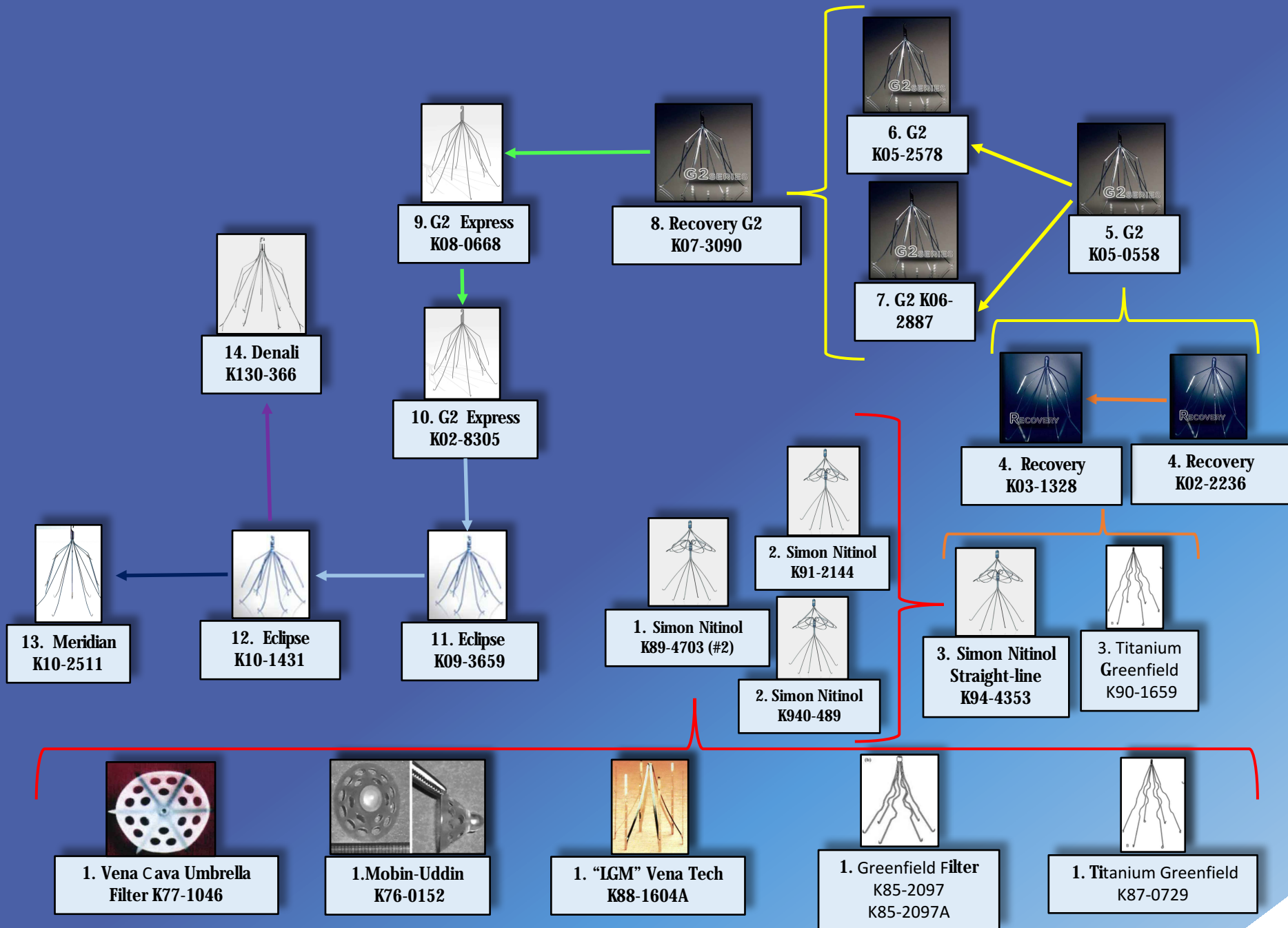
	(NMT) in the United States in 1992 as a permanently implanted medical device for the prevention of pulmonary embolism. (BPVE-01-00242737).
Late 1990s	Bard begins working on a modified design of the SNF, known as the Recovery Filter (“RNF”) that would allow for the optional retrieval of the device. [REDACTED] [REDACTED] [REDACTED]
November 1, 1999	NMT files a special 510(k) to obtain clearance for the RNF. (BPV-17-01-00051623).
December 10, 1999	The FDA sends a letter rejecting NMT’s special 510(k) application. The letter stated that clinical data was required to fully evaluate whether the modified device is substantially equivalent with regard to safety and effectiveness to the SNF. “Specifically, the clinical information should demonstrate that the RF has similar performance characteristics (e.g., deliverability, clot device trapping ability, freedom from perforation, migration and fracture) as the SNF and can safely be removed upon misplacement.” (BPV-17-01-00051623).
February 29, 2000	NMT has several communications with the FDA, which continued to state that clinical data was required “in order to define the acute (within 30 days of implant) complication profile of the device, specifically, questions of device stability must be addressed. NMT plan to perform European trial (device has received approval of the design dossier). Id. Thus, NMT planned on doing a European clinical trial. (BPV-17-01-00051623).
May 2000	NMT decides to sell RNF technology to highest bidder. Bard claimed this violated the distribution agreement and filed for arbitration. (BPVE-01-00242737).
September 2000	As of September 2000, NMT discontinued all investment in the NMT filter product line. (BPVE-01-00242737.)
May 2001	An arbitration panel rules in Bard’s favor and as a result, NMT sells its entire filter line to Bard. Due to litigation, Bard’s purchase of the filter lines, and staff changes, the European trial was never started. (BPV-17-01-00051623).
November 2002	The Bard Recovery filter was cleared through the 510(k) process as a permanent filter, the SNF being its predicate device. (BPV-17-01-00206259; BPV-17-01-00193291).
July 25, 2003	The Recovery filter is cleared as an “optional” filter. (BPV-17-01-00206259; BPV-17-01-00193291).
August 29, 2005	The G2 filter, Bard’s next permanent filter, is cleared by the FDA through the 510(k) process. (BPV-17-01-00206259; BPV-17-01-00193291).

September 2005	The Recovery filter is discontinued. (BPV-17-01-00206259; BPV-17-01-00193291).
January 15, 2008	The FDA clears Bard's second option filter, the Recovery G2. Six months later, Bard added a snare and made minor dimensional modifications to the delivery system of the Recovery G2 and called it the G2 Express.
January 14, 2010	The Bard Eclipse, which was an electropolished version of the G2 Express, is released. (BPVE-01-00761124).
April 28, 2010	Bard discontinues the G2 Express. (BPVE-01-00761124).
August 2011	Bard launches the Meridian filter, which is the Eclipse filter with caudal anchors added to increase migration resistance.
May 15, 2013	The Denali is cleared. It is Bard's newest filter and incorporated cranial anchors, caudal anchors, penetration limiters, and electropolishing.

Schedule 3 – Diagram of Predicate and Prior Predicate Devices

Bard IVC Filter Product Line with Predicate Devices

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Schedule 4 - Geometric Characteristics and Differences between RNF and Modified RNF (G2)

	SNF	RNF	Modified RNF (G2)	Notes:
Wire Thickness	.014"	.013"	.013"	
Height		41mm	39mm	
		.43" (trig		*12.7mm (Recovery) and 9mm (G2)
		Calculation is		according to McMeeking report,
Distance from Cap to Elbow	N/A (Dome)	.498" or	.3543" (9mm)	0.498" (12.65mm)for Recovery by my
Distance from Elbow to Tip	N/A	12.65mm)*		calculations
		12mm	17.75-19.75mm	
Number of Upper Struts	7 Petals	6	6	*0.4830" (12.27mm) for Recovery by
Length of Upper Strut		20mm	25mm	my calculations
Length of Legs				*RNF Diagram; BPVE-01-01059087
Angle of Upper Strut	7 Petals	52.5 degrees		
Angle at Elbow	N/A	147 degrees		*Trig salculation from measurements
Angle of Lower Strut		19.5 degrees		on document; BPV-17-01-00002728
Angle at Knee		15 degrees		*Hook thickness incorrectly reported in
Hook Curvature				above document See p.3; BPV-17-01-
Thickness of Hook	.014"	.0085"	.0105"	00002639
Chamfer	N/A	straight	curved	
Diameter Upper	28-32mm	28-33mm	30-35mm	
Diameter Lower	32-40mm	30-34mm ¹	38-42mm	

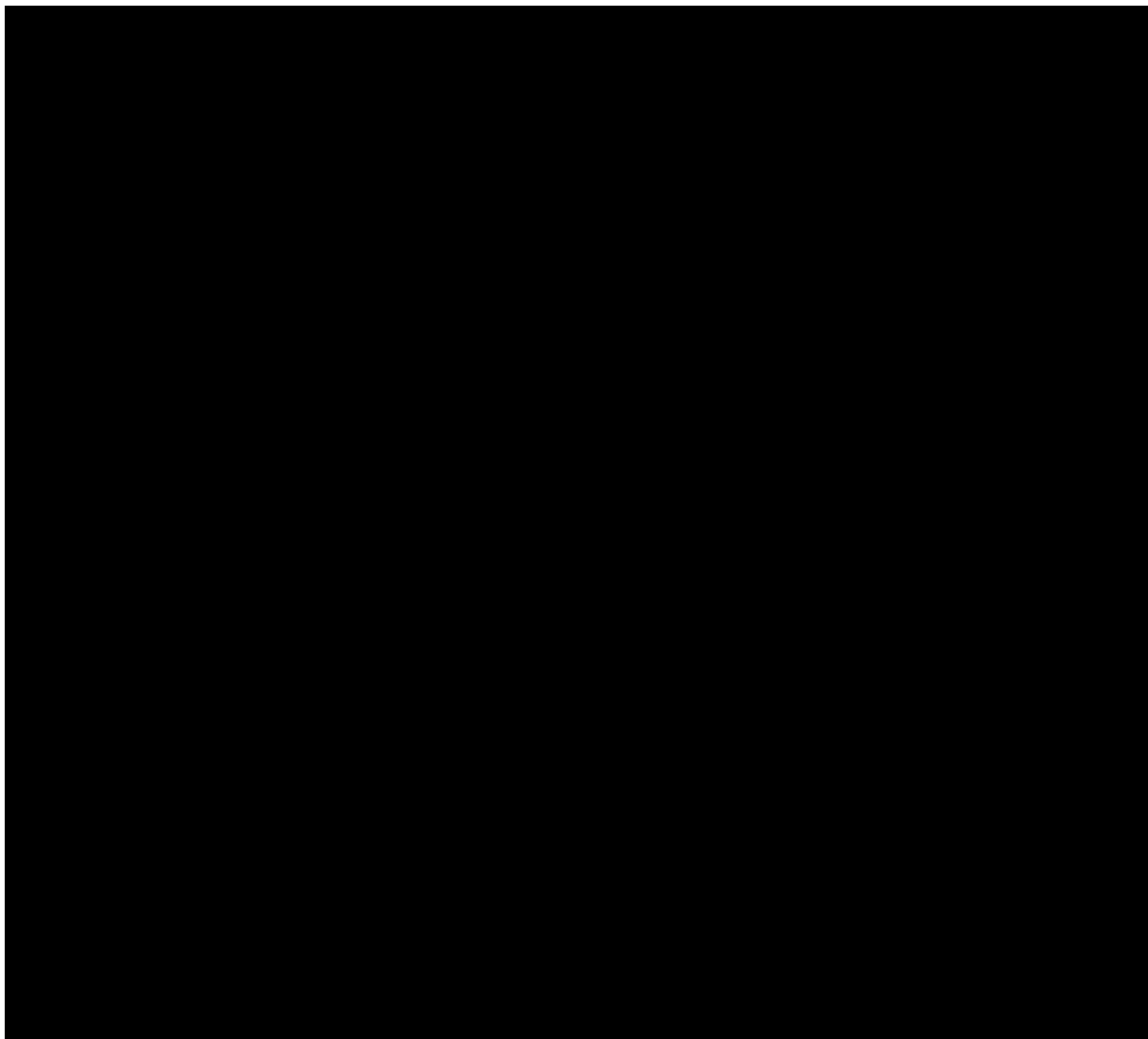
¹ NMT's original design for lower diameter is 29-34mm.

Schedule 5 - Bard Filter 510(k)s and Filter Diagrams

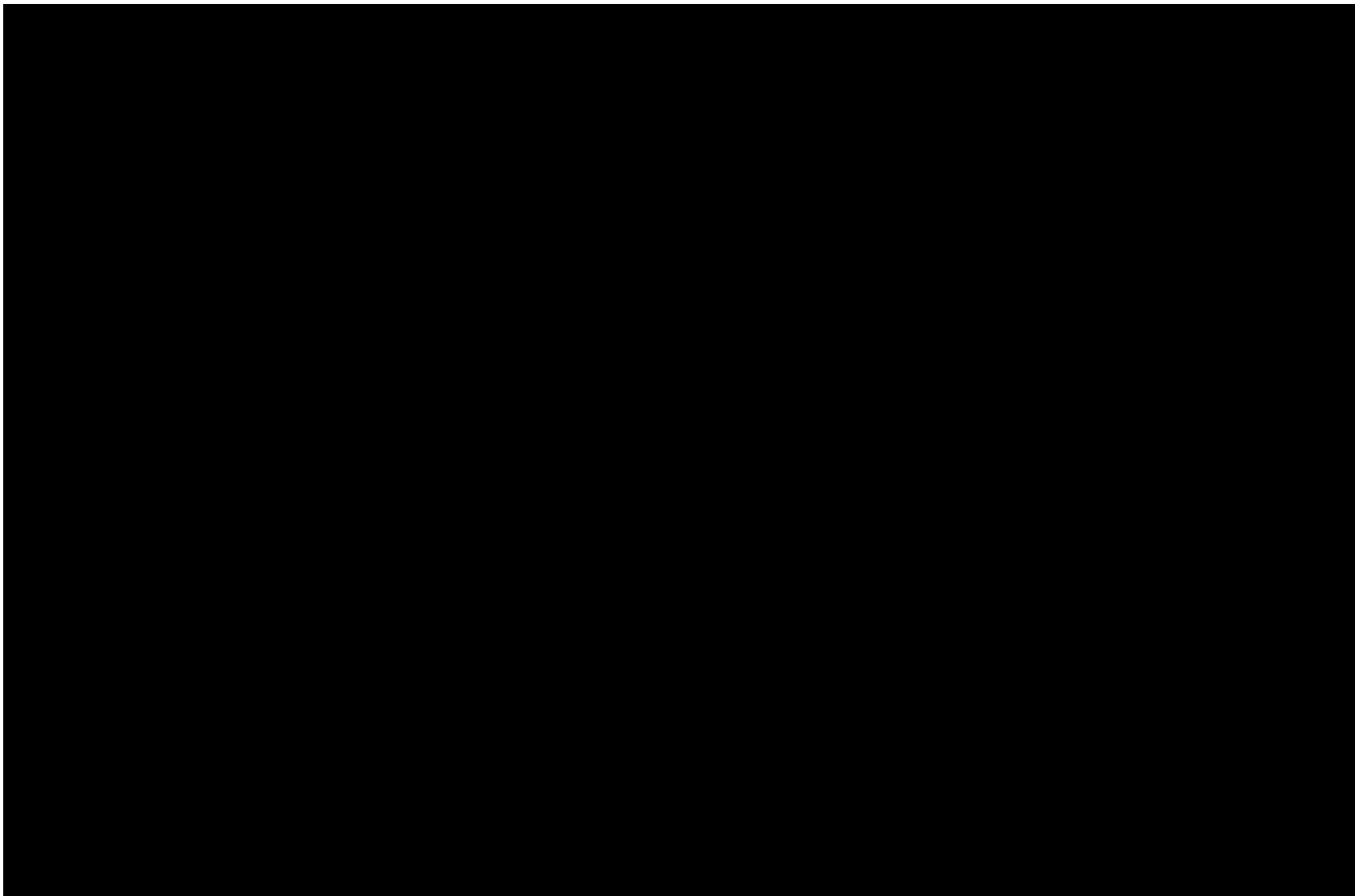
Schedule 5 - Bard Filter 510(k)s and Filter Diagrams

PRODUCT	COMPANY	CONTACT	SUBMISSION DATE	DECISION DATE	510(K) NUMBER
Simon Nitinol Filter	NMT	Jack Reinstein	7/24/1989	4/20/1990	K894703
Simon Nitinol Filter Modification	NMT	Leonard Gordon	5/13/1991	10/17/1991	K912144
Simon Nitinol Filter	NMT	Stephen J Kleshinski	1/25/1994	8/9/1994	K940489
Simon Nitinol Filter	NMT	Jonathan S Kahan	8/30/1994	4/28/1995	K944353
Simon Nitinol Filter/Straight Line System	NMT	Sherrie Coval- Goldsmith	8/2/1996	11/18/1996	K963014
Simon Nitinol Filter/Straight Line System	NMT	Sherrie Coval- Goldsmith	1/13/1997	4/16/1997	K970099
Recovery Filter System (RF-048F)	C.R. BARD	Kay Fuller	7/11/2002	11/27/2002	K022236
Recovery Filter System (RF-048F)	C.R. BARD	Mary J Edwards	4/28/2003	7/25/2003	K031328
Modification to: Recovery Filter System (RF-210F)	C.R. BARD	Karen Hutchison	3/3/2005	8/29/2005	K050558
G2 Filter System - JUG/SUB Delivery Kit (RF-320J)	BPV	Genevieve Balutowski	9/20/2005	11/25/2005	K052578
Modification to G2 Filter System-FEM Delivery Kit (RF-310F)	BPV	Genevieve Balutowski	9/26/2006	10/26/2006	K062887
Recovery G2 Filter System - FEM/JUG/SUB Delivery Kit (RF-310F, RF-320J)	C.R. BARD	Genevieve Balutowski	11/1/2007	1/15/2008	K073090
G2 Express Filter System- FEM/JUG/SUB DDelivery Kit (RF400F)	C.R. BARD	Genevieve Balutowski	3/10/2008	7/30/2008	K080668
G2 Express Filter System - FEM/JUG/SUB DELIVERY KIT	C.R. BARD	Genevieve Balutowski	8/13/2008	10/31/2008	K082305
Eclipse Filter System-FEM/JUG/SUB Delivery Kit (RF500F)	C.R. BARD	Joni Creal	11/25/2009	1/14/2010	K093659
Eclipse Filter System-FEM/JUG/SUB Delivery Kit	C.R. BARD	Joni Creal	5/21/2010	6/25/2010	K101431
Meridian Filter System- JUG/SUB Delivery Kit	C.R. BARD	Joni Creal	9/1/2010	8/24/2011	K102511
Meridian Filter System-- FEM Delivery Kit	C.R. BARD	Joni Creal	8/29/2011	10/24/2011	K112497
Denali Filter System- FEM/JUG/SUB Delivery Kit	C.R. BARD	Joni Creal	2/13/2013	5/15/2013	K130366
Denali Filter System - FEM/JUG/SUB Delivery Kit	C.R. BARD	Laurie Sang	11/10/2014	12/9/2014	K143208
Denali Filter System - FEM/JUG/SUB Delivery Kit	C.R. BARD	Laurie Sang	3/30/2016	4/29/2016	K160866

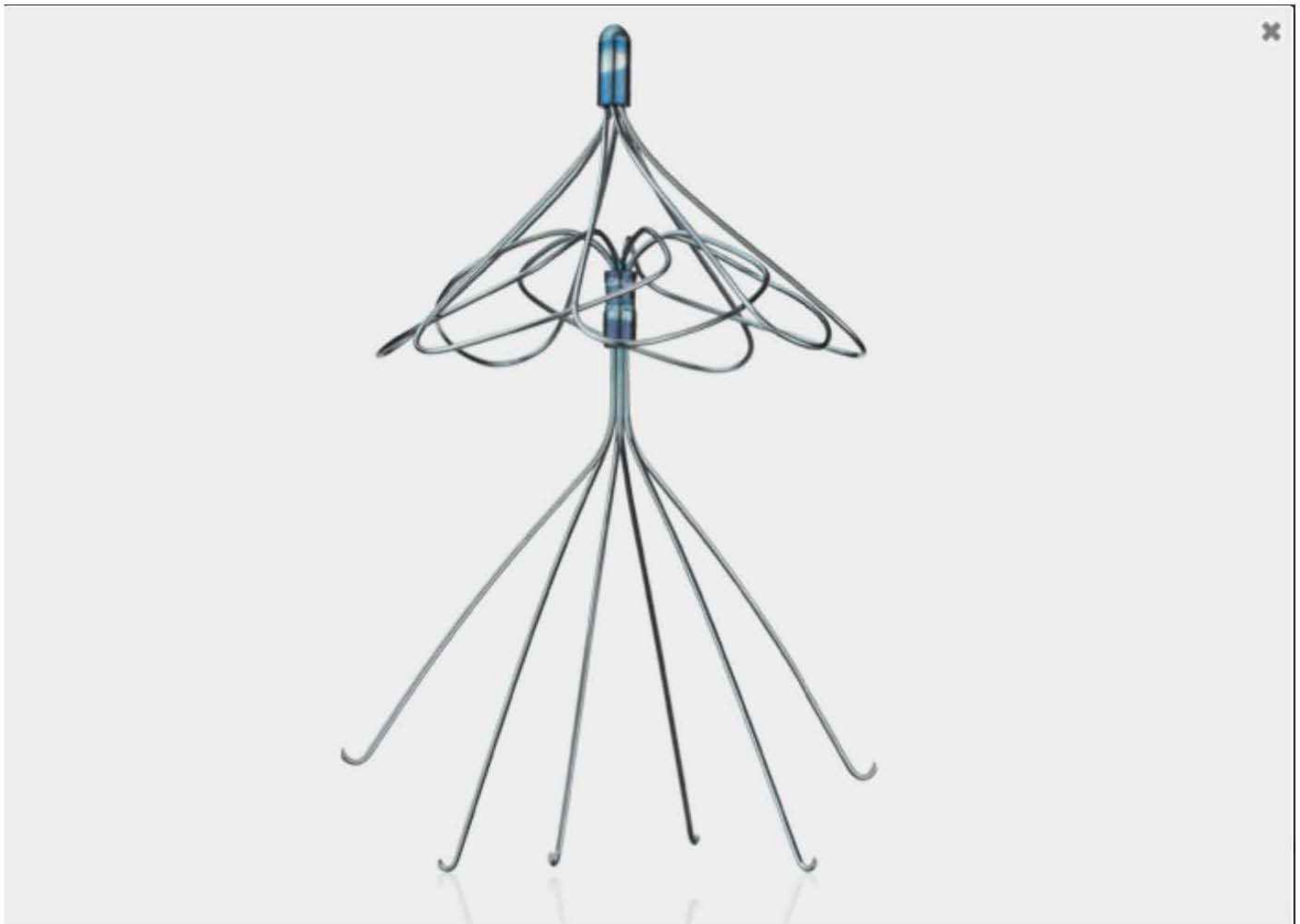
SNF



SNF



SNF

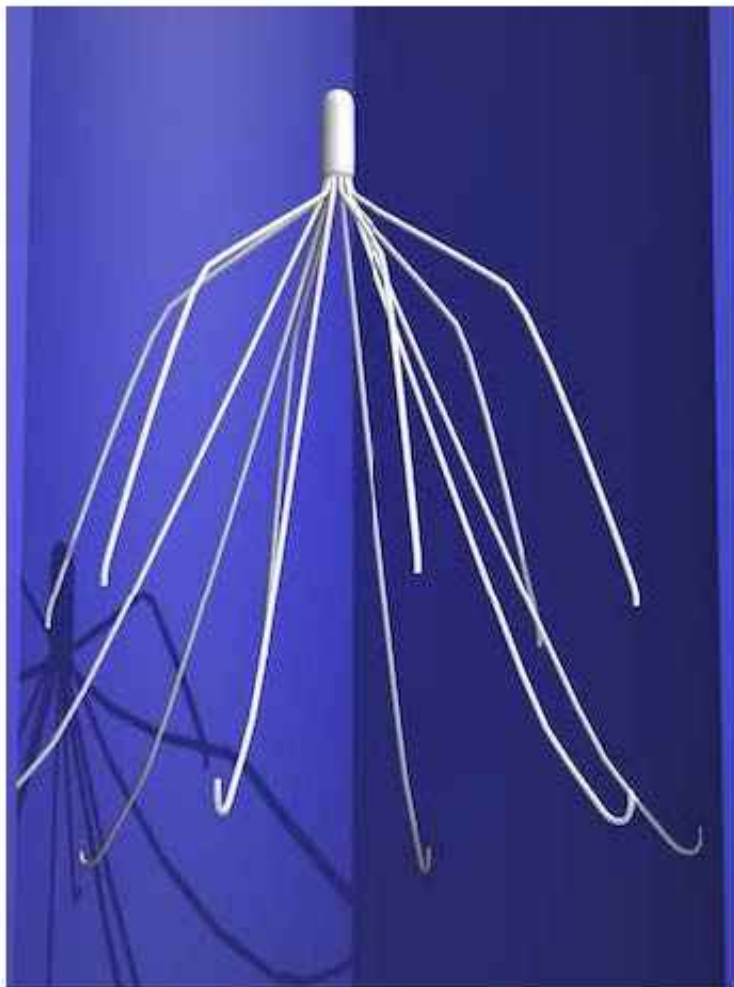


SNF

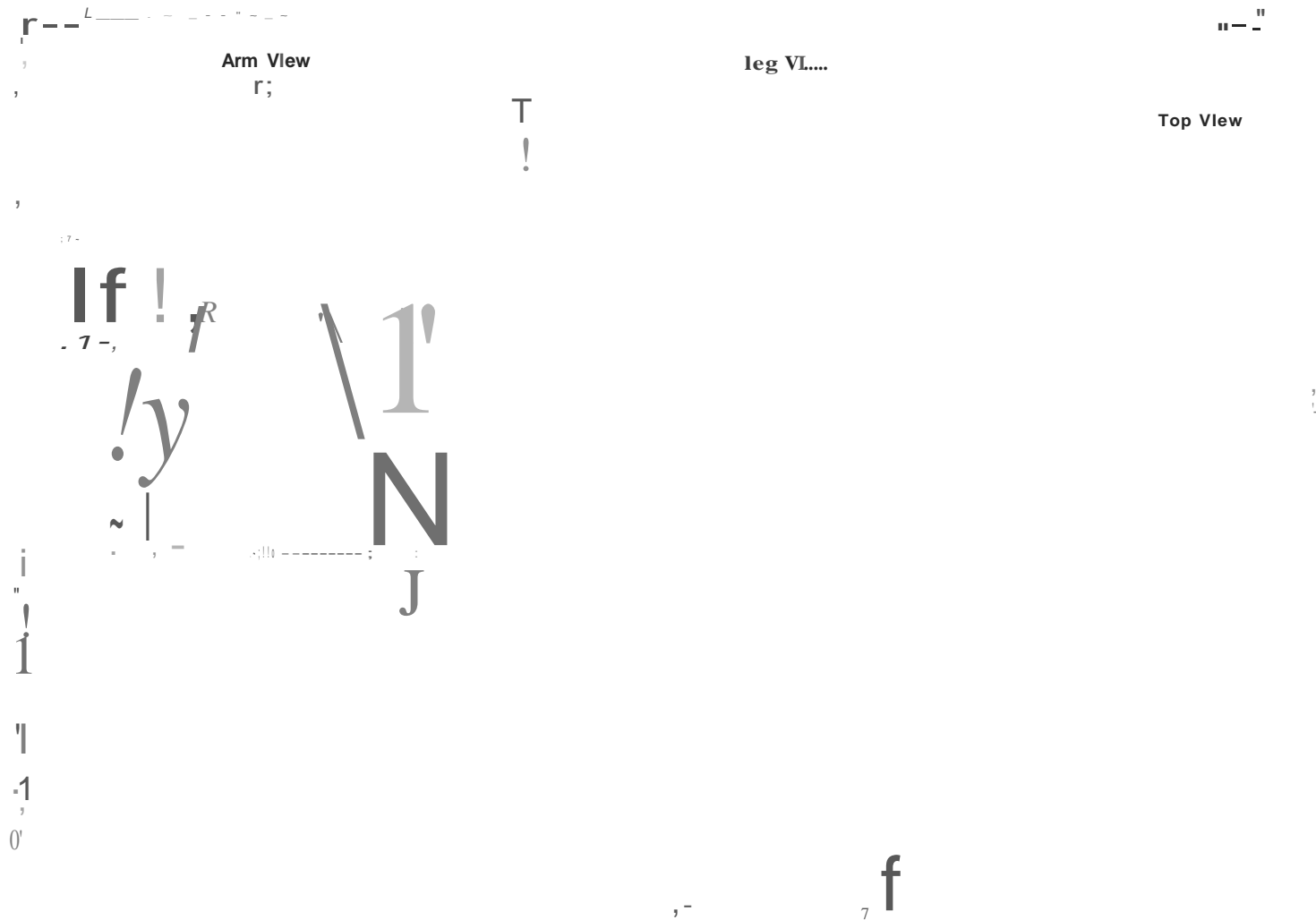
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Recovery



Recovery



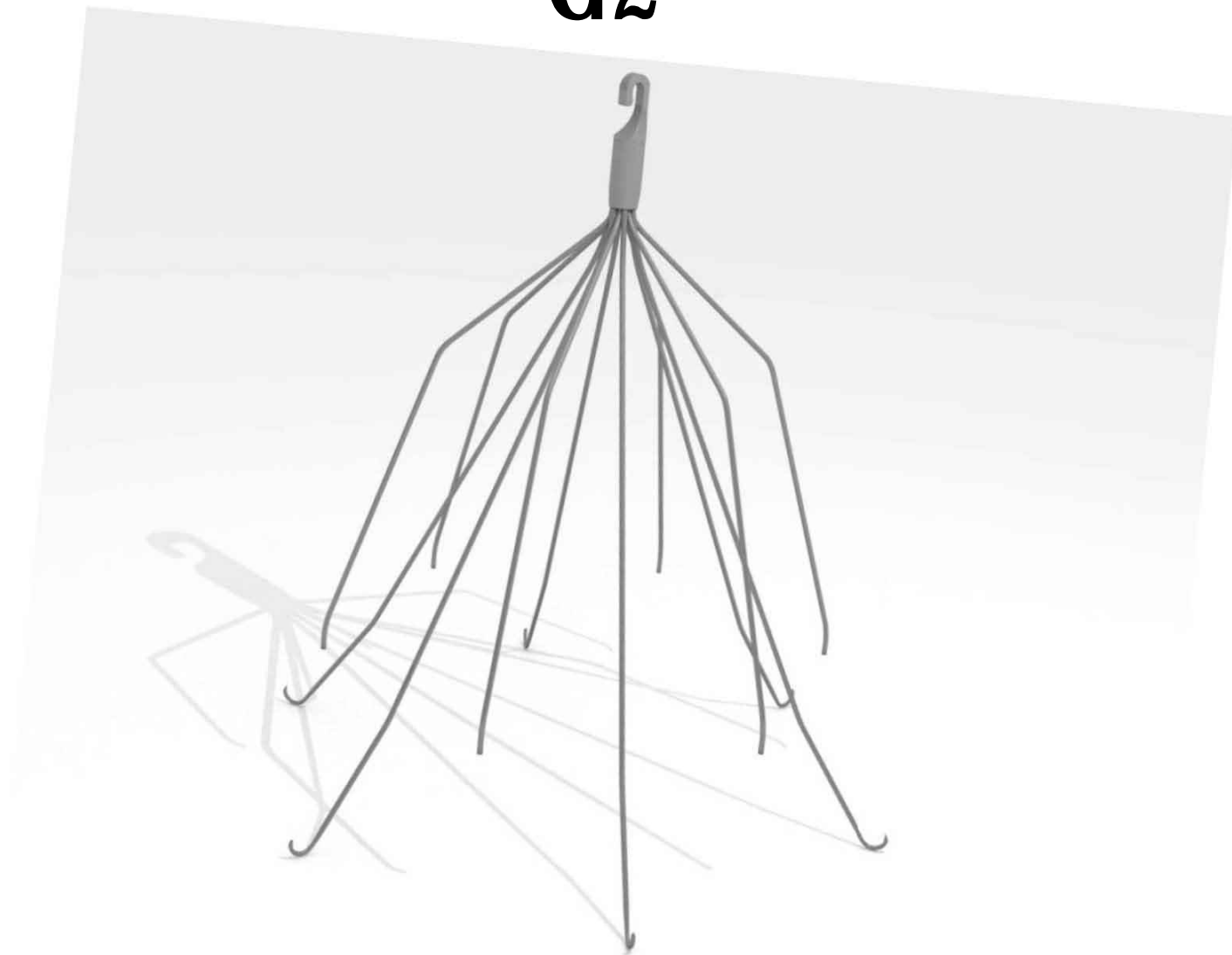
Recovery Cone Removal

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G2



G2



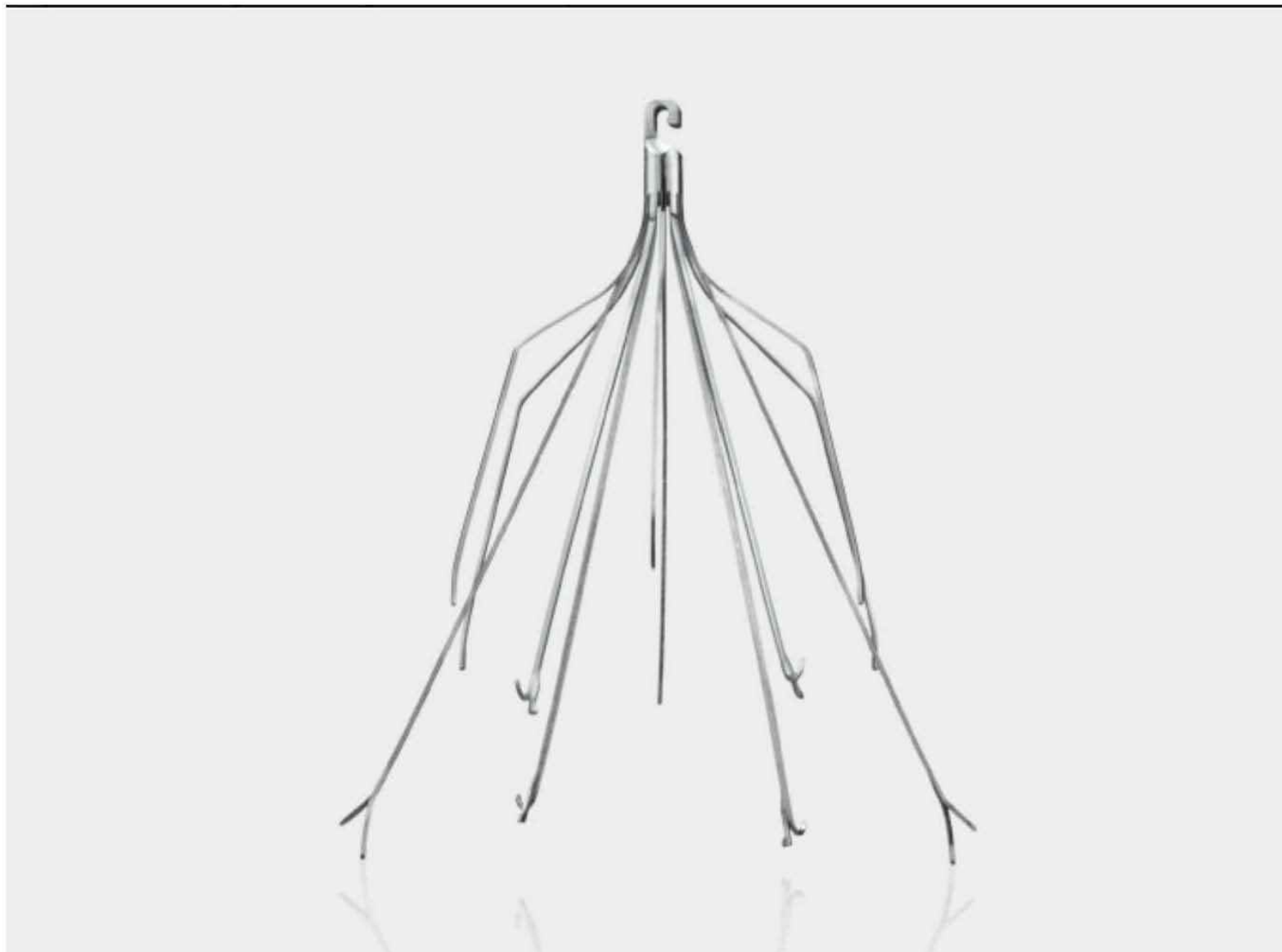
Eclipse

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Meridian



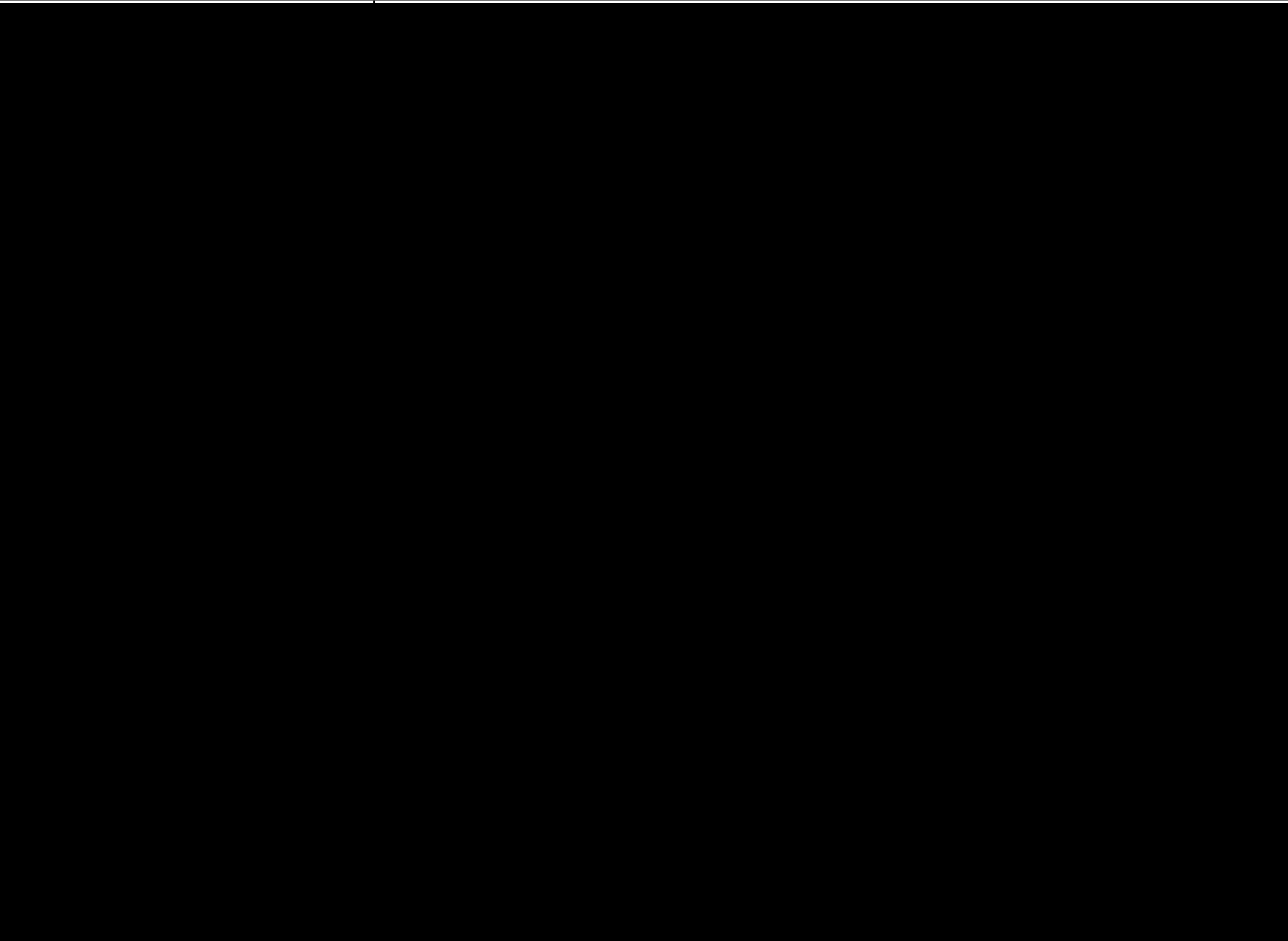
Denali



Schedule 6 – Migration Resistance Testing for RNF and G2

Schedule 6 - Migration Resistance Testing -- Recovery and Modified Recovery (G2)

Date	Description	Data/Results
8/5/1999		
2/24/2000		
4/7/2000		

6/19/2001- 6/20/2001	
12/9/2003	
2/17/2004	
2/25/2004	

3/15/2004

3/17/2004

3/17/2004

3/19/2004

3/24/2004

4/5/2004

4/21/2004

7/22/2004

12/14/2004	
2/7/2005	
2/16/2005	
3/22/2005	
5/25/2005	

8/25/2005

2/8/2006

p p

11/27/2006

1/21/2010

Schedule 7 – Clinical Studies: Complications of Bard and Other Filters

Schedule 7 – Clinical Studies: Complications of Bard and Other Filters

Category Definitions:

Category I: Bard-Sponsored Clinical Trials.

Category II: Clinical Studies by Paid Bard (or NMT) Consultants, Employees or Individuals who Received Grants, Royalties or Fees from Bard. This included authors or co-authors who indicated no conflict of interest at the time the study was published, yet indicated in a prior or subsequent study that they were either a paid consultant or employee of Bard.

Category III: Third-party Independent Studies of Bard Filters Only. These are independent studies prepared by non-Bard affiliated authors regarding only Bard filters, and whom, to our knowledge, have not previously or subsequently identified themselves as a paid Bard consultant or employee.

Category IV: Third-Party Studies of Multiple Filter Types Including Bard. These are also independent studies by authors unaffiliated with Bard, but, unlike Category III, these studies compare safety and efficacy of various filter brands and types (i.e., Gunther Tulip, OptEase and Bird's Nest) including at least one or more Bard filters in the study.

Schedule 7 – Clinical Studies: Complications of Bard and Other Filters

Clinical Studies Index:

I. Bard-Sponsored Clinical Trials

1. NMT Clinical Study of the SNF (BPVE-01-00066095 - 66109); see also, US FDA Clinical Data Summary of the Simon Nitinol Filter (BPVE-01-00280772).
2. Morris Simon, et al., Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience, Work in Progress, Radiology 1989; 172: 99-103. (BPV-17-01-00061114 -1118).
3. Murray Asch, M.D. FRCP, Study submitted (BPV-17-01-00057981 – 87); see also, Murray Asch, MD, Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter, Radiology, Dec. 2002; 225, pp. 835-844.
4. Bard Recovery G2 Filter Study - EVEREST Final Study Report [BPVE-502d-00000013 - 103].
5. S. William Stavropoulos et al. for the DENALI Trial Investigators, The DENALI Trial: An Interim Analysis of a Prospective, Multicenter Study of the Denali Retrievable Inferior Vena Cava Filter, J Vasc Interv Radiol 2014; 25:1497–505.

II. Bard Consultant Studies

6. Eric Engmann, MD and Murray R. Asch, MD, FRCPC, Clinical Experience with the Antecubital Simon Nitinol IVC Filter, JVIR 1998; 9:774 - 778.
7. Steven E. Deso, et al., Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type, Semin Intervent Radiol 2016;33:93–100.
8. William J. Grande, MD, et al., Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter, J Vasc Interv Radiol 2005; 16:1189 –1193.
9. Binkert, Christoph, A., MD, MBA, et al., Retrieval of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days, J Vasc Interv Radiol 2006; 17:299 –302.
10. Colin P. Cantwell, Frank C. Lynch, et al., Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters, J Vasc Interv Radiol 2009; 20:1193 -1199.
11. William T. Kuo, MD, et al., High-risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications, J Vasc Interv Radiol 2009; 20:1548 –1556.

12. John C. Oh, et al., Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall, *Vasc Interv Radiol* 2011; 22:70–74.
13. Kanupriya Vijay, MD, et al., Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts, *J Vasc Interv Radiol* 2012; 23:188 –194.
14. Lu Anne V. Dinglasan, MD, et al., Removal of Fractured Inferior Vena Cava Filters: Feasibility and Outcomes, *J Vasc Interv Radiol* 2012; 23:181–187.
15. Lu Anne V. Dinglasan, MD et al., Complicated Inferior Vena Cava Filter Retrievals: Associated Factors Identified at Pre-retrieval CT, *Radiology*: Volume 266: Number 1—January 2013.
16. William T. Kuo, MD, et al., Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscopic Analysis, *J Vasc Interv Radiol* 2013.
17. Ryan M. Kiefer, et al., The Value of Rotational Venography Versus Anterior–Posterior Venography in 100 Consecutive IVC Filter Retrievals, (CIRSE) 29 July 2015.
18. Vincent L. Oliva, et al., Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval, *J Vasc Interv Radiol* 2008; 19:884-889.
19. Frank C. Lynch, MD and Stephanie Kekulawela, MD, Removal of the G2 Filter: Differences between Implantation Times Greater and Less than 180 Days, *J Vasc Interv Radiol* 2009; 20:1200–1209

III. Bard Third-Party Studies

20. Timothy C. McCowan, MD et al., Complications of the Nitinol Vena Caval Filter, *JVIR* May 1992;3:401-408.
21. Clement J. Grassi, MD, et al., Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignancy, *JVIR* 1992; 3:535-539.
22. P. A. Poletti, et al., Long-term results of the Simon nitinol inferior vena cava filter, *Eur. Radiol.* 8, 289-294 (1998).
23. J. Bottomley, et al., Initial clinical experience at a single tertiary centre with the ‘Recovery’ vena caval filter (Abstract), *Peripheral Vascular Session 2B*: 4 Nov 2005: 495.
24. Sanjeeva P. Kalva, et al., Recovery Vena Cava Filter Experience in 96 Patients, *Cardiovasc Intervent Radiol* (2006) 29:559 - 564.

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Schedule 7 – Clinical Studies: Complications of Bard and Other Filters

I. Bard-Sponsored Clinical Trials

1. NMT Clinical Study of the SNF (BPVE-01-00066095 - 66109); *see also, US FDA Clinical Data Summary of the Simon Nitinol Filter (BPVE-01-00280772).*

- SNF
- 258 patients received SNF from 02/1988 - 11/1990.
- Non-randomized, prospective, multi-center study.
- 6 month follow-up for 180 pts (70%) analyzed; significant AE reported during/beyond 6 months.
- End points: assessing ease of filter placement, security of filter anchorage measured by lack of filter migration, filter complications and clot-filtering effectiveness.
- Measurement: Pre- and post-delivery vena cavography; plain radiography of the filter post-procedure and again at 3 and 6 months. Optional chest radiography, ventilation perfusion lung scans, US imaging of filter region, CT, MR, or digital-subtraction angiography, generally in symptomatic patients.
- Results:

Recurrent PE:	
Migration:	
Perforation:	
Penetration:	
Tilting:	
Occlusion:	
Fracture:	
Death:	

2. Morris Simon, et al., *Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience, Work in Progress*, Radiology 1989; 172: 99-103. (BPV-17-01-00061114 - 1118).

- SNF

- 103 Patients implanted with SNF from 02/1988 - 11/1988.
- Follow-up at 3 and 6 months.
- End points: The SNF is currently undergoing a multi-center clinical trial and is classified as an IDE by the FDA. This preliminary progress report focuses on early clinical results in 44 patients; and follow-up data of major complications in 103 patients at 17 participating centers.
- Measurement: Initial abdominal radiographs in all 44 patients in the Boston study. Plain radiography of the filter post-procedure and again at 3 and 6 months. Optional studies: US of filter region, MRI or digital subtraction angiography, chest radiography and ventilation/perfusion lung scanning.
- Results:

Recurrent PE:	2	2 Asymptomatic; 0 Symptomatic; 1 unconfirmed Symptomatic. ("Unconfirmed" means "suspected findings only").
Migration:	1	"Addendum: Since this study was submitted, one migration of a SNF has occurred and will be included in a future report."
Penetration:	0	
Dome Tilt:	24	Dome of filter was frequently observed to be tilted about 20 - 25°.
IVC Occlusion:	10	7 Symptomatic; 3 Asymptomatic; 2 unconfirmed Symptomatic.
Fracture:	0	
Death:	0	7 deaths unrelated to filter.

3. **Murray Asch, M.D. FRCP, Study submitted (BPV-17-01-00057981 – 87); see also, Murray Asch, MD, *Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter*, Radiology, Dec. 2002; 225, pp. 835-844.**

- Recovery
- 35 patients implanted with Recovery filters from 4/01 - 11/01.
- Average follow-up at 223 days (range, 4 - 522 days).
- End points: To evaluate our preliminary clinical experience with the efficacy of this filter and the safety of its retrieval in humans. Dr. Asch's data relative to complications provide clinical data to support a determination of substantial equivalence as a permanent filter.
- Measurement: Abdominal radiography 1 and 7 days after placement, then yearly. No other routine follow-up imaging because this device was placed on a compassionate basis. Appropriate imaging studies were done when an adverse event was clinically suspected. In patient 10 and all subsequent patients, routine follow-up abdominal radiographs were done to assess for possible filter migration

due to asymptomatic migration in patient 9. (Asch, Initial Experience in Humans, supra, at p. 838).

- Results:

Recurrent PE:	0		
Migration:	1	(3.7%)	
Perforation:	1	(3.7%)	“Filter leg outside vessel lumen.” (BPV-17-01-00057984).
Penetration:	3	(11.1%)	"1-2 filter legs incorporated into caval wall." <i>Id.</i>
Tilt:	2		
Occlusion:	0		
Fracture:	1	(3.7%)	
Death:	0		3 patients died unrelated to filter.

4. Bard Recovery G2 Filter Study - EVEREST Final Study Report [BPVE-502d-00000013 - 103].

- Recovery G2
- 100 Patients implanted at 11 sites from 12/7/05 - 7/24/06.
- Prospective, multi-center, non-randomized clinical study.
- 1 month post-retrieval follow-up. 56 Retrieval Patients; 6 month follow-up after placement, 33 Non-Retrieval Patients.
- End points: The EVEREST study was designed to assess the safety of retrieval, with the ultimate goal of proving substantial equivalence for this device when used as a retrievable filter.
- Measurement: AP digital subtraction Venacavography pre and post filter placement. Post-placement procedural imaging, 6 month follow-up and during filter retrieval included supine KUB in AP projection on full expiration or PA digital spot film centered on the implanted filter. 82 subjects were analyzed for Migration; 83 subjects were analyzed for PE, Fracture, Tilt >15° and Penetration/Protrusion.
- Results:

Related PE:	
Migration:	
Fracture:	
Penetration:	
Tilt:	
Occlusion:	

Death:	0		6 subjects died during follow-up; none were filter-related. (p. 70).
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5. **S. William Stavropoulos et al. for the DENALI Trial Investigators, *The DENALI Trial: An Interim Analysis of a Prospective, Multicenter Study of the Denali Retrievable Inferior Vena Cava Filter*, J Vasc Interv Radiol 2014; 25:1497–1505.**

- Denali
- 200 Patients with filter placements between 6/23/11 and 5/14/13.
- Prospective, multicenter, nonrandomized, single-arm study at 21 centers in the U.S.
- Follow-up: 2 years or for 30 days after filter retrieval. At the time of this report, 160/200 enrolled patients had undergone a retrieval attempt or been followed to 6 months with their filter in place.
- End points: To assess safety and effectiveness of the filter. Primary study endpoints included technical and clinical success of filter placement and retrieval. Patients were also evaluated for recurrent PE, new or worsening DVT, filter migration, fracture, penetration, and tilt.
- Measurement: AP and lateral digital subtraction angiograms of the vena cava before and after retrieval. At 6 month follow-up, US exam and plain radiographic film imaging of abdomen to evaluate IVC filter position. Phone consultations were performed at 3, 12, 18, and 24 months.
- Results:

Recurrent PE:	6/200	(3%)	Confirmed by pulmonary arteriography, cross-sectional imaging, altered ventilation/perfusion lung scan, or at autopsy.
Penetration:	5/200	(2.5%)	All asymptomatic. > 3 mm beyond the vena cava wall seen on venography.
Fracture:	0/179		
Migration:	0/179		
Tilt >15°:	0/200		
IVC Occlusion:	1	(1.0)	This patient was reported as a recurrent PE.
Death:	0		6 unrelated deaths.

II. Bard Consultant Studies

6. **Eric Engmann, MD and Murray R. Asch, MD, FRCPC, *Clinical Experience with the Antecubital Simon Nitinol IVC Filter*, JVIR 1998; 9:774 - 778.**

- SNF
- 74 patients with filter placements between 3/4/95- 8/21/97.
- Mean follow-up was 124 days (range, 0 - 884 days).
- End Points: We review our experience with the use of the newest IVC filter available in Canada and the value of antecubital placement.
- Measurement: Radiographs were obtained immediately after filter deployment and at 1, 7 and 30 days, 6 months and then yearly to assess filter migration. Aside from abdominal radiographs, no routine imaging studies were performed on asymptomatic patients. Clinical follow-up was available in 61 patients.
- Results: PE occurred after filter placement in 2 patients; no complications related to filter placement in other patients. The rate of recurrent PE was very low. PE was a contributing factor in 8 deaths, which all occurred within 38 days of SNF placement. Massive PEs before filter placement were the cause or a contributing factor of death in 7 of the 8 patients. In 1 of these 8 patients, there was no prior history of PE and it was impossible to determine whether the PE seen at autopsy was an asymptomatic pre-filter placement event or a post-filter placement event. One other patient's symptomatology suggested PE and the patient had a history of recurrent PE. But no investigations were performed to rule in favor of PE because the patient was already on warfarin and had an indwelling vena cava filter.

7. **Steven E. Deso, et al., *Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type*, Semin Intervent Radiol 2016;33:93–100.**

- 23 Filter types including SNF, Recovery, G2, G2X, Eclipse, Meridian and Denali.
- Reported device-specific complications from 1980 - 2014.
- End points: The purpose of this study was to evaluate the various FDA-approved IVC filter types to determine device-specific risks, as a way to help identify patients who may benefit from ongoing follow-up versus prompt filter retrieval.
- Measurement: An evidence-based electronic search (FDA Premarket Notification, MEDLINE, FDA MAUDE) was performed to identify all IVC filter types and device-specific complications.
- Results:

- * Conical Bard filters were associated with the highest reported rates of fracture: Recovery (5.5 - 25%, with an estimated incidence of 39.5% at 65.7 months), G2, G2X, Eclipse, Meridian (1.2 -12% initially, with highest reported rate of 38% at 60 months), SNF (10-16%).
- * Purely conical filters were associated with the highest reported rates of IVC perforation: Recovery (27-100%), G2/G2X/Eclipse (26-44%), SNF (25-95%), Tulip (22-78%), Celect (22-93%), and Titanium Greenfield (13-50%).
- * Migration rates $\geq 10\%$ were reported as follows: Bard Recovery (0-10%), Bard G2 (12-25%), Titanium Greenfield (7.5-15%), Tulip (2.4-12.5%), and Vena Tech (6-18.4%).
- * Filters with a cylindrical component (Vena Tech LGM, Trapease/Optease) or umbrella element (SNF - 3.5 - 50%) were associated with high rates of caval thrombosis.

8. **William J. Grande, MD, et al., *Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter*, J Vasc Interv Radiol 2005; 16:1189 –1193.**

- Recovery
- 106 patients who received filters over a 14-month period.
- End points: To evaluate initial experience with the Recovery filter as a retrievable IVC filter.
- Measurement: Before filter removal, all patients underwent CT venography or lower-extremity venous ultrasonography (US). An inferior vena cavogram was obtained before and after filter removal. 13 patients underwent imaging by abdominal plain radiography; 14 patients underwent abdominal CT imaging.
- Results: Removal was successful in 14/15 patients at a mean of 150 days post-placement.

Recurrent PE:	3	(2.8%) Symptomatic
Death:	1 possible	One patient died while undergoing thrombolytic therapy for a massive PE. The patient had a known large PE before the filter was placed and the patient's death may or may not have been caused by new PE.
Symptomatic Perforation, Fracture, Migration and Caval Thrombosis:	0	Patients were not routinely assessed by abdominal radiography for migration or fracture therefore, not all patients were evaluated for these complications. Similarly, not all patients were screened for caval thrombosis after filter placement.

9. **Binkert, Christoph, A., MD, MBA, et al., *Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days*, J Vasc Interv Radiol 2006; 17:299 – 302.**

- Recovery
- 13 patients received filters from July 2004 - January 2005 and had them removed >180 days later.
- End points: To assess the feasibility of longer dwell times (> 180 days) for the Recovery filter.
- Measurement: IVC venography was performed before and after filter retrieval.
- Results: All 13 filters were successfully retrieved after a mean dwell time of 254.2 days (range, 181- 491 days).

Tilt >10°:	2	(2.8%) Severe tilts of 20° and 25°.
Migration:	0	
Penetration:	Possibly 1	
Filter Thrombus:	0	

10. **Colin P. Cantwell, Frank C. Lynch, et al., *Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters*, J Vasc Interv Radiol 2009; 20:1193 -1199.**

- Recovery and G2.
- 241 patients: 128 received Recovery filter from 6/25/03 - 9/29/05; 113 received G2 filter from 9/20/05 - 6/22/06
- End points: To compare the Recovery and G2 filters regarding technical success of filter placement and attempted retrieval, filter tilt, migration, fracture and efficacy.
- Measurement: A digitally subtracted posteroanterior cavogram was obtained at placement, post-placement and on retrieval. After filter retrieval, a follow-up cavogram was obtained through the sheath for identification of complications.
- Results: Recovery filter retrieval was successful in 67/71 patients at a mean of 228 days; G2 filter retrieval was successful in 60/62 patients at a mean of 230 days.

Device-Related PE:	Recovery: Possibly 1
Migration:	Recovery: 9 caudal migration; 4 cranial migration. G2: 26 caudal migration; 2 cranial migration;
Fracture:	Recovery: 6; G2: 0
Tilt >15°:	Recovery: = 3; G2 = 2 (p. 1198); Recovery: = 4; G2 = 7 (Table, p. 1196)

11. William T. Kuo, MD, et al., *High-risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications*, J Vasc Interv Radiol 2009; 20:1548 –1556.

- G2 (1), Recovery (2), Gunther Tulip (8) and OptEase (2).
- 13 patients with attempted filter retrieval from Oct. 2007 - Oct. 2008.
- End points: to evaluate the safety and efficacy of aggressive alternative techniques for retrieving adherent and chronically implanted IVC filters.
- Measurement: Doppler US of the deep veins and/or CT venography or conventional venography of the iliofemoral segments before retrieval attempts. Pre-procedure cavogram.
- Results: High-risk retrieval with use of various techniques with aggressive force was successful in all 13 patients (100%).

12. John C. Oh, et al., *Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall*, Vasc Interv Radiol 2011; 22:70–74.

- Recovery (23); G2 (30); Tulip (8); OptEase (3)
- 62 patients with attempted filter retrieval from Jan. 2003 – Dec. 2008.
- The mean filter dwell time was 172 days (range 13–490 days).
- End points: to examine the feasibility and safety of removing retrievable IVC filters with struts that are tenting or penetrating the IVC wall as seen on CT imaging.
- Measurement: CT images obtained before retrieval were used to assess the integrity of the IVC filter, strut relationship to the IVC wall, and thrombus trapped in the filter. These images were used to classify the filter interactions with the IVC wall into 4 different grades: Grade 0 (strut fully within the IVC lumen);

Grade 1 (strut external but immediately adjacent to the IVC lumen; likely reflecting "tenting" of the IVC wall); Grade 2 (strut completely outside the lumen); and Grade 3 (strut that contacts adjacent organs and retroperitoneal structures).

- Results:

Filter Type	Grade 0	Grade 1	Grade 2	Grade 3
Recovery	23 (100%)	15 (65.2%)	15 (65.2%)	12 (52.2%)
Recovery G2	27 (90.0%)	21 (70.0%)	17 (56.7%)	13 (43.3%)
Gunther Tulip	4 (50.0%)	6 (75.0%)	5 (62.5%)	1 (12.5%)
OptEase	2 (66.7%)	3 (100.0%)	1 (33.3%)	0 (0.0%)

13. Kanupriya Vijay, MD, et al., *Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts*, J Vasc Interv Radiol 2012; 23:188 –194.

- Recovery, G2 and G2 Express.
- 548 patients presenting for IVC filter retrieval between April 2004 - Nov. 2010.
- End points: To increase the understanding of risks of IVC filter fracture and embolization and the safety of removing fractured filters via retrospective review of a prospectively collected database of fractured IVC filters.
- Measurement: Magnified and non-magnified fluoroscopic and spot magnification inspection of all filters to evaluate filter position, orientation, and integrity. Flush cavography with digital subtraction angiography to document absence of filter thrombus. Additional oblique flush cavograms to better delineate which portions of the filter or fragments were accessible for intraluminal capture.
- Results: A total of 63 fractured filters (12%) with 77 component fractures were identified. Fractures involved 12 Recovery, 41 G2, and 10 G2 Express filters. The incidence of fracture increased with longer filter dwell times. The overall arm and/or leg fracture rate for Recovery, G2, and G2 Express filters was 6%. Success rates for removal of the non-fractured component and fractured components were 98.4% and 53.4%, respectively. The distal embolization rate of fractured filter components was 13%. The majority of embolized filter elements were identified in the lungs. All distal embolic events were clinically silent. One patient had three filter arms migrated to the heart and one leg in the right lung near the hilum. One patient had symptoms related to a fractured filter.

14. Lu Anne V. Dinglasan, MD, et al., Removal of Fractured Inferior Vena Cava Filters: Feasibility and Outcomes, J Vasc Interv Radiol 2012; 23:181–187.

- Recovery, G2 and Celect.
- 148 patients with filter retrievals between Jan. 2002 - Dec. 2010.
- End points: Retrospective, single center review of IVC filter retrievals over an 8-year period identified patients in whom there was an attempt to retrieve fractured filters and struts to examine the feasibility/outcomes of removing fractured retrievable IVC filters.
- Measurement: Four fractures were identified on pre-procedure CT, with the remainder discovered on digital radiographs obtained at the time of retrieval.
- Results: Of the 148 filters were retrieved, 15 were fractured: 6 Recovery filters (40%), 7 G2 filters (47%) and 2 Celect filters (13%). 5 patients reported symptoms. Strut retrieval was not attempted or failed in 3 G2 and 2 Recovery filters. Of the 19 fractured struts (4 filters had 2 fractured struts each), 10 struts (53%) were contained in the IVC; 9 struts (47%) were outside the IVC, with embolization to the heart (1 Recovery), to the pulmonary artery (1 Recovery; 1 G2) or having at least half their length within the extraluminal tissues adjacent to the IVC (1 Recovery; 2 G2; 1 Celect). In 1 patient (Recovery), a fractured strut, previously seen penetrating the small bowel, could not be found and was believed to have been excreted.

15. Lu Anne V. Dinglasan, MD et al., *Complicated Inferior Vena Cava Filter Retrievals: Associated Factors Identified at Pre-retrieval CT*, Radiology: Volume 266: Number 1—January 2013.

- Recovery, G2, G2X, Celect, Gunther Tulip, OptEase, and Option.
- Single-center, retrospective review of filter retrievals between Jan. 2002 and July 2011.
- 48 patients with complicated retrievals; 48 control subjects with uncomplicated retrievals.
- Measurement: Age- and sex-matched control subjects with standard IVC filter retrieval were used for comparison. Pre-retrieval CT images evaluated for tilt angle, tip embedding and degree of strut perforation.
- Results: The filters retrieved in the complicated retrieval group of 48 patients included 26 G2 (54%), 8 Recovery (17%), 6 Celect (13%), 4 Gunther Tulip (8%), 2 OptEase (4%), 1 Option (2%) and 1 G2X (2%). The filters retrieved in the control group of 48 subjects included 23 G2 (48%), 20 Recovery (42%), 4 Gunther Tulip (8%), and one Celect (2%). The most important factors leading to

complicated filter extraction were interrelated parameters: tip embedding and tilt angle. The preretrieval CT appearance of tip embedding, increased tilt angle, higher-grade perforation, and longer dwell times are factors associated with complicated IVC filter retrieval.

16. William T. Kuo, MD, et al., *Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscopic Analysis*, J Vasc Interv Radiol 2013.

- Bard filters: G2X (23), G2 (9), Eclipse (3), Recovery (4) and SNF (1). Non-Bard filters: ALN (1), Celect (7) and OptEase (2).
- 50 patients presenting over 2.5 years with fractured, embedded and/or penetrating IVC filters refractory to standard retrieval methods.
- End points: to evaluate the safety and effectiveness of complex retrieval methods, to analyze the resultant clinical outcomes in patients suffering from filter-related morbidity, to characterize adherent tissue on embedded filters, and to elucidate mechanisms of filter fracture.
- Measurement: All patients underwent complex filter retrieval after failure of standard methods; resultant clinical outcomes were evaluated. All fractured components were studied with electron microscopy.
- Results: Retrieval was successful in all 50 cases. Among 61 fractured components from conical filters, 35 had extravascular penetration. EM revealed fracture modes of high-cycle fatigue (53), overload (6) and indeterminate (2). 24 filter patients (48%) were asymptomatic but demonstrated worrisome fractures, penetrations, and/or embolizations identified radiographically. 26 patients (52%) were actively suffering from filter-related morbidity and 2 had already experienced life-threatening events secondary to volvulus and cardiac tamponade from penetrating and/or embolized filter components. The 26 symptomatic cases include 1 G2X filter fracture with component in extravascular retroperitoneum and penetration of 2 components through the left caval wall; and 1 SNF removed because of severe pain from bowel penetration.
- Conclusion: The risk of filter fracture increases after 408 days of implantation and is associated with symptomatic extravascular penetration and/or intravascular embolization.

17. Ryan M. Kiefer, et al., *The Value of Rotational Venography Versus Anterior–Posterior Venography in 100 Consecutive IVC Filter Retrievals*, (CIRSE) 29 July 2015.

- Bard filters: Recovery (2), G2 (21), G2X (5), Meridian (2), Eclipse (15), Denali (5). Non-bard filters: Celest (25), Tulip (15), Option (8), Optease (1) and ALN (1).
- 100 patients.
- End points: To compare the utility of rotational venography to AP venography prior to IVC filter removal. Accurately detecting filter complications is important for safe and successful retrieval as tip-embedded filters require removal with non-standard techniques.
- Measurement: The rotational venograms from 100 consecutive IVC filter retrievals over a 35-month period were evaluated retrospectively. The AP view of the rotational venogram was examined separately from the full series by a radiologist blinded to alternative imaging and operative findings. The venograms were evaluated for tip embedding, filter fracture, filter thrombus, and IVC thrombus.
- Results: AP venography correctly identified 31 tip-embedded filters with two false positives for an accuracy of 70%. Rotational venography correctly identified 58 tip-embedded filters with one false positive for an accuracy of 98%. AP venography correctly identified filter fracture in 6 of 17 patients with one false positive for an overall accuracy of 88%; Rotational venography correctly identified filter fracture in eight patients with zero false positives for an overall accuracy of 91%. Rotational venograms allow for more accurate detection of tip-embedded IVC filters compared to AP views alone.

18. Vincent L. Oliva, et al., *Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval*, J Vasc Interv Radiol 2008; 19:884-889.

- Recovery G2
- 120 patients with filter placed between September 2005 - September 2006 at a single center in Canada.
- Mean implant time in 51 patients was 53.4 days +/- 44.2 (range, 7 - 242 days).
- End points: The first generation filter was redesigned because of concerns about strut fracture and migration. The main objective of our study was to evaluate whether the new characteristics of the Recovery G2 filter would compromise its retrievability. Primary endpoint was retrieval without major complications; secondary end points included tilt, migration, penetration, fracture, caval occlusion and perforation.

- Measurement: Inferior vena cavogram at the start of retrieval procedure and repeat cavogram immediately afterward to assess the IVC for injury.
- Results: 51 of the 120 (42.5%) patients met the criteria for removal. Removal was successful in all 51 patients. Of those 51 patients, the following complications were identified:

Penetration:	9	(18%)	Asymptomatic
Fracture:	0		
Migration:	2	(3.9%)	Both caudal migrations. Asymptomatic.
Tilt >15°:	6	(12%)	Asymptomatic

19. Frank C. Lynch, MD and Stephanie Kekulawela, MD, *Removal of the G2 Filter: Differences between Implantation Times Greater and Less than 180 Days*, J Vasc Interv Radiol 2009; 20:1200–1209

- G2
- 174 patients that had filters placed between Sept. 2005 - Dec. 2007.
- End points: To investigate whether filters implanted for longer periods (> 180 days) are more difficult or hazardous to remove.
- Measurement: Digital subtraction angiography of the IVC during filter placement. All patients underwent duplex ultrasonography of the lower extremities to exclude presence of DVT before their removal procedure. Vena cavogram was obtained during the removal procedure. Interval cross-sectional imaging of the filters with CT was performed for other clinical reasons in 47/174 patients.
- Results: 170 of 174 G2 filters were successfully removed. Four filters ultimately could not be removed: 2 were severely tilted with filter apex and central arms endothelialized (at implant days 134 and 218); 2 had asymptomatic caval occlusion (at implant days 199 and 370).

Penetration:	76	(44%)	This rate is much higher than previously reported.
Fracture:	6	(3.4%)	All with implantation times > 180 days.
Migration:	21	(12%)	Greater than or equal to 20 mm. 20 caudal; 1 cranial.
Tilt >15°:	24	(13.8%)	
Caval Occlusion	2		Both asymptomatic.

III. Bard Third-Party Studies

20. Timothy C. McCowan, MD et al., *Complications of the Nitinol Vena Caval Filter*, JVIR May 1992;3:401-408.

- SNF

- 20 patients with filter placements between 9/20/88 - 12/5/90.
- Average follow-up was 14 months (range, 1-29 months).
- End points: We studied the insertion and postplacement complications of the SNF.
- Measurement: Anteroposterior inferior vena cavograms were obtained prior to filter placement. Plain radiographs and clinical evaluation 1 and 6 months and then yearly after filter placement. Clinical and radiologic follow-up data were available for 15 of the 20 patients.
- Results:

Recurrent PE:	0	
Penetration:	5	Asymptomatic. 1 acute and 4 at follow-up.
Fracture:	2	Asymptomatic. Found during follow-up abdominal radiograph (1 at 12 months and 1 at 24 months).
Migration:	1	Asymptomatic.
Caval Thrombus	4	
Death	0	5 deaths occurred during the follow-up period. None was determined to be filter-related, although autopsy confirmation was unavailable.

21. Clement J. Grassi, MD, et al., *Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignancy*, JVIR 1992; 3:535-539.

- SNF
- 24 patients; filters placed over a 13-month period.
- Follow-up: 3 and 6 months post filter placement
- End points: Preliminary experience with this filter suggests a slightly higher rate of IVC occlusion overall (7% - 9%) than reported for other filters. This study was performed to evaluate the prevalence of IVC occlusion with MR imaging following SNF insertion and any associated factors that might explain this higher occlusion rate.
- Measurement: Pre- and post-procedure inferior vena cavograms were obtained; plain radiography of the filter within 24 hours after placement and at 3 and 6 months.

- Results: 5 IVC occlusions. Demonstrated in MR imaging with spin-echo and gradient-echo techniques performed in 10 symptomatic patients with leg swelling at follow-up. Results indicate that the SNF has a higher frequency of filter-associated IVC occlusion than previously recognized. Since asymptomatic patients did not undergo imaging, the actual rate of vena caval occlusion may be even higher. This patient group includes a high proportion with pelvic or renal malignancy (54%, 13 of 24). All 5 patients with IVC occlusion had an underlying genitourinary or renal neoplasm; 2 of these 5 died of their tumor several weeks later.

22. P. A. Poletti, et al., *Long-term results of the Simon nitinol inferior vena cava filter*, Eur. Radiol. 8, 289-294 (1998).

- SNF
- 114 patients with filters placed between Oct. 1990 - Dec. 1995.
- Average 6-month follow-up; collection of data was terminated in March 1996.
- End points: The purpose of the present retrospective study was to evaluate the long-term results of patients who have undergone placement of SNF in two institutions.
- Measurement: 38 patients underwent dedicated radiologic follow-up protocol including abdominal radiography Doppler sonography and CT. The position of the SNF was documented immediately after placement by means of repeat venacavography, and an abdominal plain film was obtained within the first week after filter placement.
- Results:

Recurrent PE:	5	(4.4%)	Fatal in 3 cases (2.6%).
Penetration:	36	(94.7%)	Demonstrated on CT. Asymptomatic
Struts in contact with Adjacent Organs:	29	(76.3%)	Demonstrated on CT. Asymptomatic.
Fracture:	6	(15.8%)	Demonstrated on Abdominal x-ray.
Migration:	0		
Caval Thrombosis:	4	(3.5%)	

23. J. Bottomley, et al., *Initial clinical experience at a single tertiary centre with the 'Recovery' vena caval filter (Abstract)*, Peripheral Vascular Session 2B: 4 Nov 2005: 495.

- Recovery
- 51 patients with filters placed from Feb. 2003 - June 2005.

- The mean duration of placement was 97.6 days (ranging from 6-454 days).
- End points: To retrospectively review initial clinical experience using the Recovery IVC filter in a single center.
- Measurement: Patient notes and radiology reports were used to identify: indications for IVC filtration, complications on filter insertion and/or retrieval and duration of filter implantation prior to removal.
- Results:

Tilt:	1	1/17 (6%) failed retrieval due to tilting.
Migrations:	0	

24. Sanjeeva P. Kalva, et al., *Recovery Vena Cava Filter Experience in 96 Patients*, Cardiovasc Intervent Radiol (2006) 29:559 - 564.

- Recovery
- 96 patients with filters placed between Jan. 2003 - Dec. 2004.
- Mean clinical follow-up period: 160 days. Mean imaging follow-up period: 80 days
- End points: to assess the clinical safety and efficacy of the Recovery filter. Efficacy was assessed by the occurrence of PEs during clinical and imaging follow-up. Safety was assessed based on the technical difficulties during deployment/retrieval and the occurrence of filter-related complications during follow-up.
- Measurement: Follow-up CT examinations of the abdomen and chest were evaluated for filter-related complications and PE, respectively.
- Results:

Recurrent PE:	1	(3%)	Symptomatic.
Penetration:	11	(27.5%)	In 5 of 11 patients, the filter arms were seen protruding into adjacent organs: duodenum (4) and liver (1). 3 of the 11 patients, the filter legs were seen 2 mm outside the caval wall without obvious penetration of any organ. All asymptomatic.
Fracture or acutely bent arms:	3	(7.5%)	In 1 patient, the broken arm migrated to pancreas; in the other 2, the fractured arms were attached to the main device protruding into aorto-caval space. Asymptomatic.
Migration:	1		(To the pancreas). Asymptomatic.
Caval Thrombosis:	0		

25. **Jeffrey E. Hull, MD, and Scott W. Robertson, PhD, *Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration*, J Vasc Interv Radiol 2009; 20:52–60.**

- Recovery
- 16 patients.
- Mean clinical follow-up period: 160 days. Mean imaging follow-up period: 80 days
- End points: To report on the evaluation and management of Bard Recovery filter limb perforation, fracture and migration.
- Measurement: In 2007, all patients who received a Bard Recovery filter at a single institution were contacted for consultation and follow-up abdominal CT. All available images were reviewed for filter limb perforation, fracture, and migration.
- Results:

Early images in 9 patients (mean, 30 days; range, 0–126 d +/- 40):			
Perforations	5	56%	A total of 12 arm perforations in 5 patients (56%) and 1 leg perforation in 1 patient (11%)
Fracture:	0		
Migration:	0		

Follow-up examination in 14 patients (2/16 lost to follow-up) with final images (mean, 899 days; range, 119 – 1,218 d +/- 320):			
Perforations	14	100%	Arm perforations in all 14 patients (100%); leg perforation in 5 (36%). A total of 61 arm perforations and 10 total leg perforations.
Fracture:	3	21%	4 arm fractures with migration in 3 patients. All fractured arms migrated. 2 patients had symptoms related to fracture and migration.
Migration:	3	21%	1 migration to right ventricle; 1 into pulmonary artery; 1 into adjacent retroperitoneum; and 1 into legs of the filter
Recurrent PE:	0		No clinical evidence of recurrent PE.

26. William Nicholson, MD, et al., *Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade*, Arch Intern Med, August 9, 2010.

- 28 Recovery filters and 52 G2 filters.
- 80 patients who received Recovery or G2 filters from Apr. 2004 - Jan. 2009. The average time between filter implantation and assessment of filter integrity for the Recovery filter was 1498 days, or approximately 50 months. For the G2 filter, the average time interval was 717 days, or approximately 24 months.
- End points: to determine the prevalence of fracture and embolization of the Recovery and G2 vena cava filters
- Measurement: Subjects underwent fluoroscopy to assess the filter's integrity. Embolized struts were localized by fluoroscopy. Echocardiography and cardiac computed tomography were performed in patients with fragment embolization to the heart.
- Results:

Fracture:	Recovery: 7/28 (25%) G2: 6/52 (12%)
Migration:	Recovery: 6/7 patients with fractures had at least 1 fragment embolize to the heart (n = 5) or lungs (n = 1). G2: 2/6 patients with fractures had asymptomatic end-organ fragment embolization.
Death:	Recovery: 1

27. Matthew D. Tam, MD, et al., *Fracture and Distant Migration of the Bard Recovery Filter: A Retrospective Review of 363 Implantations for Potentially Life-Threatening Complications*, J Vasc Interv Radiol 2012; 23:199–205.

- Recovery
- 363 patients with filters placed between July 2003 - May 2006.
- 106 patients presented for filter retrieval, and 97 patients had their filters successfully removed at an average interval of 3.8 months (range, 3 d to 18.3 mo). A total of 131 patients were alive with the filter in situ with a mean follow-up interval from filter placement of 46.2 months (range, 1 d to 85.9 mo). A total of 135 patients had died with the filter in situ, at a mean interval from filter placement of 16.7 months (range, 2 d to 76.6 mo).
- End points: To report the occurrence of fracture of the Recovery filter and incidence of potentially life-threatening complications associated with fractured fragment migration.

- **Measurement:** Retrospective review of the departmental inventory database was used to identify consecutive Recovery filter placements at a single tertiary-care center. All images (retrieval cavagrams, plain radiographs, and computed tomography [CT] scans of the chest, abdomen, pelvis, and lumbar spine) were reviewed by using the image archive system. The following were evaluated: 130 chest CT scans, 153 abdominal CT scans, 254 chest radiographs, 148 radiographs of the abdomen/pelvis, and 106 cavagrams.
- **Results:**

Fracture:	20	5.5%	A total of 26 limb fractures in 20 patients (prevalence, 5.5%; incidence, 7.2%). Asymptomatic. Authors provide Kaplan-Meier graph and data estimating 39.5% fracture rate at 5.5 years.
Migration:	-	-	A total of 8 limbs (30.8%) migrated to pulmonary arteries, 7 limbs (26.9%) were in iliac/femoral veins, and seven limbs (26.9%) remained near the filter. One limb (3.8%) was found in each of the following sites: right ventricle, renal vein, and outside the IVC at the level of the filter; one limb could not be located.
Death:	0		Of the 20 patients with filter fractures, 3 died of unrelated causes.

28. Hearn W. Charles, MD, et al., *G2 Inferior Vena Cava Filter: Retrievability and Safety*; J Vasc Interv Radio 2009; 20:1646 - 1051.

- G2
- 140 patients with filters placed from Oct. 2006 - June 2008.
- End points: Filter retrieval success rate, mean implantation time, filter tilting (> 15°) and migration (change in cephalocaudal position of > 2 cm).
- **Measurement:** Pre-retrieval cavogram and repeat post-retrieval cavogram.
- **Results:** Of the 140 patients who had filters placed, 26 (19%) were referred for filter retrieval; all 26 were successfully retrieved.

Tilt >15°:	5	18.5%	
Migration:	0		
Fracture:	0		
Caval Occlusion:	0		

29. **M. Cura, *Computed tomography evaluation of inferior vena cava Bard G2 filters* (Abstract), Scientific Session 1 IVC Filters, Venous Thromboembolic Disease, March 14, 2010.**

- 154 patients
- Follow up CT of the abdomen (mean, 105 days; range, 1-773) in 63 patients.
- End points: to evaluate the G2 Bard Recovery filter for inferior vena cava and retroperitoneal complications.
- Measurement: This is a retrospective analysis. The images of all patients who had follow up contrast enhanced CT of the abdomen were assessed for filter tilting, migration, caval wall penetration, thrombus within the filter, filter fracture, caval injury and retroperitoneal complications.
- Results:

Tilt > 15°:	27 (42%)	
Penetration into IVC tributaries:	14 (22%)	Penetration into lumbar veins in 11 (17%); right ovarian vein in 2 (3%); into duplicated renal vein in 1 (1%).
Perforation:	15 (23%)	Involving 25 legs or arms (1 to 4 legs or arms per filter). One perforation was extending into the duodenum and one into the wall of the aorta.
IVC thrombus > 25%:	3 (4%)	
Inferior Migration:	2 (3%)	
Fractures:	0	

30. **Xiaoli Zhu, MD, PhD, et al., *Retrievability and Device-Related Complications of the G2 Filter: A Retrospective Study of 139 Filter Retrievals*, J Vasc Interv Radiol 2011; 22:806–812.**

- G2
- 139 patients; a retrospective study of all G2 retrievals from 2005 - 2009 at a single institution.
- A total of 118 filters were removed, with a mean indwelling time of 131.8 days (range, 3-602 d).
- End points: to evaluate the retrievability and device-related complications of the G2 filter in light of the recent FDA warning in August 2010 about adverse events "related to a retrievable filter remaining in the body for long periods of time" and recommending "removal when feasible and clinically indicated."

- Measurement: Images were retrieved from our imaging archiving system, including digital subtraction inferior vena cavagrams obtained during filter placement and retrieval, any CT scan that included the filter in the acquisition, and all available CT pulmonary angiography studies. 131 pairs of pre- and post-placement cavagrams and 39 CT scans were available for analysis.
- Results:

Penetration	33	25.2%	There were 9 cases with more than one limb penetration. 4 limbs penetrated the duodenal wall, one penetrated the aortic lumen, and 10 were seen abutting the vertebral body.
Migration:	17	13%	
Fracture:	2	1.4%	
Tilt >15 °:	22	16.7%	
IVC Occlusion:	3	2.2%	
PE Breakthrough:	2	1.4%	Defined as “new PE occurring after IVC placement.” Confirmed on CT pulmonary angiography; associated with significant filter tilt and migration, 14 and 6 days post placement.

31. Bruno Damascelli, MD, et al., *Use of a Retrievable Vena Cava Filter with Low-intensity Anticoagulation for Prevention of Pulmonary Embolism in Patients with Cancer: An Observational Study in 106 Cases*, J Vasc Interv Radiol 2011; 22:1312–1319.

- G2
- 106 patients with 107 filters placed from Oct. 2005 - Dec. 2009.
- Routine clinical follow-up took place monthly. Patients were followed up for a mean of 319.4 days, (range of 118-1,388 days).
- End points: to evaluate a retrievable IVC filter in combination with low-intensity oral anticoagulation for prevention of PE in patients with malignancy complicated by thromboembolic disease.
- Measurement: Multidetector computed tomography performed for preliminary evaluation per study protocol at the same time for the pulmonary vessels as for the popliteal/femoral/ iliac/caval axis. Radiologic follow-up with multidetector CT was performed at 3 months and 6 months. Vena cavograms were obtained before and after placement and before and after retrieval, with contrast agent.
- Results:

Penetration	1	0.9%	
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Migration:	1	0.9%	
Fracture:	1	0.9%	
Tilt >15 °:	6	5.7%	
IVC Occlusion:	4	3.7%	1 symptomatic.
Recurrent PE:	3	2.8%	
Death	0		

32. Tianzhi An, MD, et al., *Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations*, J Vasc Interv Radiol 2014; 25:941–948.

- G2
- 829 patients with filters placed from Oct. 2005 - Feb 2010 at a single tertiary care center; 684 had follow-up imaging and qualified for the study.
- The mean clinical follow-up period was 22.7 months +/- 24.5 (range, 0-83.4 mo). The mean imaging follow-up interval was 14.1 months +/- 19.9 (range, 0-83.4 mo).
- End points: The goal of this retrospective study was to assess the prevalence of filter fracture and its clinical sequelae in a cohort of patients who underwent G2 filter placement at our institution.
- Measurement: All images were retrieved from the image archiving database in our health care system. Imaging studies included cavograms performed at filter retrieval and plain radiographs and computed tomography scans of the chest, abdomen, pelvis, and lumbar spine.
- Results:

Fracture:	13	1.9%	All asymptomatic. There were 16 fractured limbs in 13 patients. 9 of the 16 fractured limbs had distant migration to the pulmonary arteries (4); right ventricle (2), pericardium (1), iliac vein (1), and kidney (1). 4 fracture limbs remained near the filter; the remaining 3 could not be located. No life-threatening events occurred in patients with filter fracture during the study time frame. The estimated 5-year fracture prevalence was 38% (95% confidence interval, 22.9%, 54.8%).
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IV. Third-Party Studies of Multiple Filter Types Including Bard

33. Christos A. Athanasoulis, MD, et al., *Inferior Vena Caval Filters: Review of a 26-year Single-Center Clinical Experience*, *Radiology* 2000, 216:54 - 66.

- SNF (598), Bird's Nest (265), Greenfield standard (458), Greenfield slim (22), Greenfield titanium (140), Mobin-Uddin (29), Protect-cath (3), Tempofilter (3) and Vena Tech (247).
- 1,731 patients with filters placed between 1973 - 1998 at a single hospital.
- End points: to present data we have collected from a 26-year clinical experience with caval filters and to submit observations relevant to their introduction, adoption, application, effectiveness, and safety. A computer search of hospital discharges during 1973 - 1998.
- Measurement: Data from direct imaging of the filter were available in 43.9% (760 of 1,731) of the patients. This included abdominal radiography, CT, or venacavography. In 467 patients, chest radiographs were available and used to confirm the filter had not migrated to the chest.
- Results: For all cases of observed post-filter PE, the highest prevalence was 8.4% (38 of 455) with the standard Greenfield 24-F filter, and the lowest was 3.0% (18 of 594) with the Simon Nitinol device. For fatal post-filter PE, the prevalence was 6.3% (16 of 255) for the Bird's Nest, 5.3% (24 of 455) for the standard Greenfield, and 2.0% (12 of 594) for the Simon Nitinol filter.

Data are percentages	SNF	Mobin-Uddin	Greenfield Standard	Bird's Nest	Greenfield Titanium	Greenfield Slim	Vena Tech
Post-Filter PE:	3.0	7.1	8.4	7.0	4.5	5.0	5.9
Fatal Post-Filter PE:	2.0	3.6	5.3	6.3	2.2	0.0	3.8
Caval Thrombosis:	3.7	32.1	3.3	0.4	0.7	10.0	2.0

34. Matthew A. Corriere, MD, et al., *Vena cava filters and inferior vena cava thrombosis*, *J Vasc Surg* 2007;45:789-94).

- Permanent IVC filters (P-VCFs): Greenfield (162), SNF (1), TrapEase (1), Vena Tech (1). Retrievable IVC filters (R-VCFs): OptEase (13), Gunther Tulip (3), Recovery (8).
- 189 patients with filters placed between Jan 2000 - Dec. 2004 at a single center.
- Median follow-up of 8.5 months.
- End points: This review examines our single-center experience with the use of both R- VCF and P-VCF, with particular emphasis on complications associated with their use.

- Measurement: Identified patient records were reviewed, including hospital charts, outpatient clinic notes, operative reports, interventional radiology reports, and noninvasive vascular laboratory records.
- Results:

Migration:	0	
Vena Cava Thrombosis:	4	1 TrapEase (100%); 3 OptEase (23.1%).

35. Munier Nazzal, et al., *Complications Related to Inferior Vena Cava Filters: A Single-Center Experience*, Annals of Vascular Surgery Volume 24, Issue 4, Pages 480-486, May 2010.

- TrapEase (224), Greenfield (95), Gunther-Tulip (42), Recovery (34) and SNF (5)
- 400 patients with filters placed between Jan. 2002 - Jan. 2006
- End points: We analyzed our experience with IVC filters during a 4-year period with a focus on complications and the differences in complication rates among the different filter types.
- Measurement: Retrospective study involving chart reviews of patients. CT scans were evaluated for IVC thrombosis, presence of clots entrapped within the filter, penetration, tilt, fracture, and migration.
- Results:

	Recovery	SNF	Tulip	TrapEase	Greenfield
IVC Thrombosis:	3 (8.8%)	1 (20%)	2 (4.8%)	11 (4.9%)	2 (2.1%)
Post-Insertion PE:	0	N/A	1 (2.4%)	2 (0.9%)	3 (3.2%)
Tilt/Malposition:	4 (11.8%)	N/A	1 (2.4%)	1 (0.5%)	0
Migration:	0	0	0	0	0

36. Sanjeeva P. Kalva, MD, et al., *Suprarenal Inferior Vena Cava Filters: A 20-Year Single-Center Experience*, J Vasc Interv Radiol 2008; 19:1041–1047.

- SNF (5), Recovery (1), Greenfield (29), Vena Tech (3), Bird's Nest (1), TrapEase (22), OptEase (3), Tulip (6).
- 70 patients with suprarenal filters placed between 1988 - 2007.
- Mean follow-up of 137 days +/- 953 days.

- End points: To assess the clinical safety and efficacy of suprarenal IVC filters during long-term follow-up including complications.
- Measurement: retrospective study, collecting data about patients who underwent suprarenal IVC filter placement at their institution. CT pulmonary angiography or ventilation-perfusion scintigraphy were reviewed for clinically suspected post-filter PE. Abdominal CT scans reviewed for migration, fracture and penetration. Available CT chest scans also reviewed for PE.
- Results: 1 post-filter PE confirmed on CT. No Caval thrombosis. No filter migration > 2cm. 1 fracture . 2 penetrations of IVC wall with filter legs seen in the pancreas or liver (1 Recovery; 1 Greenfield).

37. Umang Swami, MD, et al., *Experience with Vena Cava Filters at a Large Community Hospital and Level-I Trauma Center: Indications, Complications, and Compliance Barriers*, 2014, Vol. 20(5) 546-552.

- SNF, G2 Express, Eclipse, Vena-Tech, TrapEase, Celect and Gunter Tulip.
- 254 patients with filters placed between Jan. 1, 2009 - 2012.
- Short follow-up with a median of 108.5 days on 96 patients.
- End points: retrospective review at our institution to evaluate our application of widely recommended guidelines of use of IVCF and to formulate a protocol for improved patient follow-up and IVCF retrieval rates.
- Measurement: Records of consecutive patients discharged from our institution (Saint Barnabas Hospital) were reviewed, including complications based on the follow-up CT scans.
- Results:

Asymptomatic Complications on Follow-Up:								
	SNF	G2 Express	Eclipse	TrapEase	Vena Tech	Bird's Nest	Tulip	Celect
Migration above renal veins:				4	1	1	3	0
Struts outside IVC:	1						1	
Tilt:								
Penetrating IVC, medial leg almost abutting aorta wall:		1						
Prongs indenting vertebral body and aorta:			1					
Hook in IVC wall:							1	

38. Riyadh Karmy-Jones, MD, et al., *Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: An AAST Multicenter Study*, J Trauma 2007; 62: 17 - 25.

- Recovery (224), Tulip (152) and Optease (37).
- 446 patients with filters placed between Jan. 1, 2005 - Dec. 31, 2005.
- Retrieval at 50 ± 61 days after placement. Follow-up to July 1, 2006.
- End points: Multi-center study to assess procedures of different trauma centers placing filters, incidence of R-IVCF removal, reasons for non-removal and differences between P-IVCF and R-IVCFs. Primary outcomes included major complications (migration, PE, and symptomatic caval occlusion).
- Results:

	Recovery	Gunther Tulip	OptEase
Migrations:	3 (1.3%) (2 with tilt>15°)	0	0
Tilt >15°:	2	0	0
Break-through PE:	1 (0.4%)	1 (0.6%)	0
Symptomatic Caval Occlusion:	2 (1.0%)	0	4 (11%)

39. Hyun S. Kim, MD, et al., *A Comparison of Clinical Outcomes with Retrievable and Permanent Inferior Vena Cava Filters*, J Vasc Interv Radiol 2008; 19:393-399.

- Retrievable Filters (RF): Recovery (40), G2 (77), OptEase (260), Gunther Tulip (50).
- Permanent Filters (PF): TrapEase (214), Vena Tech (35), Greenfield (25), Bird's Nest (1).
- 427 patients with RF and 275 patients with PF placed between 1/1/02 - 12/31/06.
- Overall, the mean follow-up duration was 11.5 months +/- 14.4.
- End points: To compare the clinical effectiveness of retrievable and permanent inferior vena cava filters.
- Measurement: Retrospective chart review of all hospital records including radiology reports. Routine surveillance objective radiologic studies were not performed in the absence of clinical symptoms to assess patients for thrombotic complications.
- Results for Different Retrievable Filters:

	Recovery (40)	G2 (77)	Tulip (50)	OptEase (260)
New PE (Symptomatic):	2 (5%)	5 (6.5%)	2 (4.0%)	11 (4.2%)
Symptomatic IVC Thrombosis:	0	0	1 (2.0%)	1 (0.4%)

40. Lisa D. Duffett, et al., *Outcomes of patients requiring insertion of an inferior vena cava filter: a retrospective observational study*, Blood Coagulation and Fibrinolysis 2014, 25:266–271.

- Recovery (133), G2 (85), Gunther Tulip (87), Celect (22)
- 336 patients with filters placed between Jan. 1, 2007 - Dec. 31, 2010.
- Median follow-up of 16.3 months.
- End points: retrospective observational study to evaluate the safety and efficacy of IVC filters over a 4-year period including complication rate, and the appropriateness of insertion and removal of IVC filters.
- Measurement: Electronic and paper medical records were reviewed; descriptive statistics were used to present patient characteristics and outcomes.
- Results: Sixty-eight patients (20% of all patients) had one or more filter-related complications. IVC filter use in our study was associated with a substantial rate of complications including thrombotic complications. PE occurred in 3% of patients while the filter was in place, all within the first month of filter insertion. This is higher than the 3-month incidence of PE in patients receiving full-dose anticoagulation and no IVC filter (1.6%) previously reported.

41. Emily A Wood, et al., *Reporting the impact of inferior vena cava perforation by filters*, 2014, Vol. 29 (7) 471–475.

- G2, Recovery, Eclipse, and SNF, Celect, TrapEase, Greenfield, Gianturco-Roehm and Gunther-Tulip
- 391 reported cases of perforations in the MAUDE database between 1/1/00 - 12/31/11.
- End points: To investigate IVC wall perforation that has occurred over time and was not specifically related to any filter mechanical defect or issues during deployment. We reviewed 3,311 adverse events of IVC filters reported in MAUDE for incidence of perforation.
- Results:

391 (12%) cases of IVC perforation were reported in 9 devices.				
G2	Recovery	Celect	Greenfield	Gianturco- Roehm

168 (43%)	59 (15%)	46 (12%)	19 (41%)	14 (31%)
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42. Jessica M. Andreoli, MD, et al., *Comparison of Complication Rates Associated with Permanent and Retrievable Inferior Vena Cava Filters: A Review of the MAUDE Database*, J Vasc Interv Radiol 2014; 25:1181–1185.

- Permanent Filters: Greenfield, Vena Tech, TrapEase, Simon Nitinol and Bird's Nest
- Retrievable Filters: Recovery, G2, G2X, G2 Express, Eclipse, and Meridian; Celect, OptEase, Gunther Tulip, Option and ALN.
- 1,606 adverse events involving 1,057 IVC filters reported between 1/1/09 - 12/31/12.
- End points: To compare the safety of PFs and RFs by reviewing the FDA Manufacturer and User Facility Device Experience (MAUDE) database for adverse events.
- Results:

	Bard RFs (1,063)	Celect (157)	OptEase (107)	Tulip (51)	Option (11)	ALN (5)
Fracture	288 (27.1%)	31 (19.7)	9 (8.4%)	3 (5.9%)	2 (18.2%)	1 (20%)
Migration:	12 (11.3%)	15 (9.6%)	26 (24.3%)	7 (13.7%)	0	1 (20%)
Limb Embolization:	131 (12.3%)	16 (10.2%)	2 (1.9%)	0	0	1 (20%)
Tilt:	165 (15.5%)	19 (12.1%)	6 (5.6%)	3 (5.9%)	1 (9.1%)	0
Penetration:	161 (15.1%)	47 (29.9%)	2 (1.9%)	3 (5.9%)	1 (9.1%)	0
VTE/PE:	15 (1.4%)	3 (1.9%)	1 (0.9%)	0	1 (18.2%)	1 (20%)
IVC Thrombus:	21 (1.9%)	5 (3.2%)	7 (6.5%)	0	0	0

43. Shayna Sarosiek, MD, et al., *LESS IS MORE - Indications, Complications, and Management of Inferior Vena Cava Filters - The Experience in 952 Patients at an Academic Hospital With a Level I Trauma Center*, JAMA Intern Med. 2013;173(7):513-517.

- Permanent Filters: TrapEase, Bird's Nest. Retrievable Filters: Option, Tulip, OptEase, G2/G2X and Eclipse.
- 952 patients with filter use between August 1, 2003 and February 28, 2011.

- The median retrieval time after filter placement was 122 days (range, 2-1931 days) in 71 patients.
- End points: To review the medical records of patients with IVC filters to determine patient demographics and date of and indication for IVC filter placement, as well as complications, follow-up data, date of IVC filter retrieval, and use of anticoagulant therapy.
- A retrospective review of IVC filter use at Boston Medical Center, a tertiary referral center with the largest trauma center in New England. During the period of this medical record review. 59.6% of patients having no follow-up data or no mention of the filter at the time of follow-up care.
- Results: 10 serious filter-related complications, including 9 filter migrations and 2 filter fractures.

44. Anas Renno, et al., *A single center experience with retrievable IVC filters*, *Vascular* 2015, Vol. 23(4) 350–357.

- Celest (38%), "Bard" (31.4%), Option (26.2%), Tulip (4.1%) and Recovery (0.2%).
- 232 patients with filters placed between July 2007 - August 2011.
- End points: In this retrospective review, we are evaluating our single institution-based center experience using retrievable filters. The objective is to evaluate their retrieval and associated complications during the period of insertion.
- Measurement: The medical records of patients implanted with retrievable IVC filters at a single institution were reviewed. Pre- and post-placement cavograms were performed.
- Results: 2 reported fractures of G2 filters. One was retrieved in pieces; the other had one leg stuck around with the IVC with no change in the leg position as demonstrated by CT scan one year after retrieval.

45. Aaron S. Bos, MD, et al., *Indwelling and Retrieval Complications of Denali and Celest Infrarenal Vena Cava Filters*, *J Vasc Interv Radiol* 2016; 27:1021–1026.

- Denali and Celest.
- 333 patients with filters placed between April 1, 2013 - Mar. 31, 2015.
- Follow-up abdominal CT at 138.9 days on 58 Denali filters and 88.3 days on 58 Celest filters.

- Follow-up CT pulmonary angiography or V/Q scan at 108 days on 17 Denali filters and 71.8 days on 23 Celect filters.
- End points: The present study compares indwelling and retrieval complications between Denali and Celect filters.
- Results:

	Denali (171)	Celect (162)
Penetration:	1 (1.7%)	12 (20.7%) (7 into adjacent viscera)
Tilt:	1 (1.7%; tilt = 42°)	15 (25.9%; range, 16° - 21°)
Migration:	1 (1.7%)	2 (3.4%)
Fracture:	0	0
Break-through PE:	2 (11.8%)	5 (21.7%)

Exhibit D (Cont.)

DOCUMENT SUBMITTED UNDER SEAL

Schedule 8 – Timeline of Substantive Changes to SNF, Recovery, and G2 Lines IFUs

Schedule 8 – Timeline of Substantive Changes to SNF, Recovery, and G2 Lines IFUs**A. RECOVERY FILTER****Recovery IFU April 2002 (Fem, Rev. 0)**

Complication	Warnings	Potential Complications	Other Sections
Tilt	“The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation in the inferior vena cava.”	No	N/A
Perforation	No	“ <i>Perforation of the vena cava wall.</i> This may occur if improper insertion technique is not utilized.”	N/A
Migration	No	“ <i>Migration of the filter.</i> This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized”	N/A
Fracture	No	No	N/A
Death	No	No	N/A
Permanent Use	No	No	N/A

(BPV-17-01-00042515-525)

Recovery IFU December 2002 (Fem, Rev. 1 (Perm))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU) “The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation in the inferior vena cava.”	No	N/A
Perforation	No	(Note: Same as previous IFU) “ <i>Perforation of the vena cava wall.</i> This may occur if improper insertion technique is not utilized.”	N/A
Migration	No	(Note: Same as previous IFU) “ <i>Migration of the filter.</i> This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized”	N/A
Fracture	No	No	N/A
Death	No	No	N/A
Permanent Use	No	No	<i>Precautions:</i> “The safety and effectiveness of the <i>Recovery Filter</i> for use as a retrievable or temporary filter have not been established.”

(BPV-17-01-00042651–661)

- This December 2002 Recovery Filter System IFU did not make any changes to the April 2002 IFU regarding perforation, migration, or fracture. (BPV-17-01-00042651–661)
- Bard’s December 2002 IFU was issued primarily to comply with the FDA’s required addition of the phrase “The safety and effectiveness of the Recovery Filter for use as a retrievable or temporary filter have not been established,”¹ and for other FDA-mandated changes. (BPV-17-01-00042663 & BPV-17-00035840).

¹ See FDA November 27, 2002 Letter. (BPV-17-01-00042677) The FDA required that addition to the IFU because it “determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm.” *Id.*

Recovery IFU December 2003 (Fem, Rev. 2 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU.) “The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation in the inferior vena cava.”	No	N/A
Perforation	No	(Note: Same as previous IFU.) “ <i>Perforation of the vena cava wall.</i> This may occur if improper insertion technique is not utilized.”	<i>Instructions for Use - Clinical Experience:</i> “The only other adverse event reported was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, minus the hook.”
Migration	No	(Note: Same as previous IFU) “ <i>Migration of the filter.</i> This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized”	<i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
Fracture	No	No	<i>Instructions for Use - Clinical Experience:</i> “The only other adverse event reported was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, minus the hook.”
Death	No	No	N/A

Permanent Use	No	No	<i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.
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(BPVE-01-00435559-561)

- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant Recovery IFU under at least two different Bates numbers. (BPV-17-01-00000246-248 & BPV-17-00042560-562)
- The Warnings section differs from the previous IFU but not in any relevant substantive way.
- Note: The December 2003 Recovery Cone Removal System IFU may be found at BPV-17-01-00113014.

Recovery IFU August 2004 (Fem, Rev. 6 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU) “The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation in the inferior vena cava.”	Incorrect release or positioning of the filter. Incorrect orientation of the filter.	N/A
Perforation	No	“Perforation or other acute damage of the IVC wall. This may occur if proper insertion technique is not utilized. ”	<i>Instructions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”
Migration	“Filter movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in oversized IVC with diameters exceeding 28 mm. Migrations to the heart or lungs have also been reported in association with the filter being overwhelmed by large clot burdens larger than 28 mm.”	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in oversized IVC with diameters exceeding 28mm. Migrations to the heart or lungs have also been reported in association with the filter being overwhelmed by large clot burdens over 28mm. which have expanded the caval wall beyond the maximum indicated caval diameter (28 mm), dislodging the filter from its deployed position. ”	(Note: Same as previous IFU) <i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
Fracture	“Filter fracture is a known complication of vena cava filters. Most fractured limbs are discovered at time of retrieval. A small minority of patients has reported complaints relating to cardiac symptoms and one case reported retrieval through open-heart surgery. Most cases of filter fracture, both those reported through adverse event reporting and the published literature, are without consequence, and the effect is not discernible.”	“Filter fracture is a known complication of vena cava filters. Most fractured limbs are discovered at time of retrieval. A small minority of patients has reported complaints relating to cardiac symptoms and one case reported retrieval through open-heart surgery. Most cases of filter fracture, both those reported through adverse event reporting and the published literature, are without consequence, and the effect is not discernible.”	<i>Instructions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”

Death		“All these above complications have been associated with serious adverse events such as medical intervention and/or death.”	
Permanent Use			(Note: Same as previous IFU) <i>General Information</i> : “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.

(BPV-17-01-00101996–2006)

- Language struck through on chart is struck through on IFU (possible draft). Portions are illegible.

Recovery IFU October 2004 (Fem, Rev. 3 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU) “The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation within the IVC.”	No	
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall.”	(Note: Same as previous IFU) <i>Instructions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”
Migration	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	(Note: Same as previous IFU) <i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
Fracture	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) <i>Instructions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”

Death		(Note: Same as previous IFU) “All these above complications have been associated with serious adverse events such as medical intervention and/or death.”	
Permanent Use			(Note: Same as previous IFU) <i>General Information</i> : “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.”

(BPV-17-01-00236585-632)

- The December 2004 version of the Recovery IFU (Rev. 4) is substantively identical in all relevant ways. (BPVE-01-00438100-147 with foreign language counterparts and Revision number 4 & BPV-COMP-00001317-319). The same December IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant Recovery IFU. (BPV-17-01-00112988-290)
- The December 2004 version was accompanied by a Dear Doctor letter advising of the potential complications listed in the October 2004 version (Rev. 3). It is not clear, therefore, whether the October 2004 version was issued publicly. (BPV-17-01-00112991-3010).

Recovery IFU (EU) April 2005 (Fem, Rev. 2 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	“The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation within the IVC.”	No	N/A
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall.”	N/A
Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	<i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
Fracture	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	<i>Instructions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”
Death	No	“All these above complications have been associated with serious adverse events such as medical intervention and/or death.”	N/A

Permanent Use	No	No	<i>General Information:</i> “The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.
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(BPVE-01-00130402-404)

- This IFU is undated but is included in an April 2005 G2 Design Dossier (applicable for EU CE) and is referred to as the “current IFU.” (BPVE-01-00130402-404)
- The Recovery filter was discontinued in the U.S. in September 2005 with the launch of G2. (BPV-17-01-00206259)

B. RECOVERY G2 (EUROPEAN)**Recovery G2 IFU (EU) November 2005 (Jug (Optional))**

Complication	Warnings	Potential Complications	Other Sections
Tilt	“The Recovery G2 Filter System – Jugular/Subclavian is designed for Jugular/Subclavian approaches only. Never use the Recovery G2 Filter System – Jugular/Subclavian for femoral approaches, as this may result in improper Recovery G2 Filter orientation within the IVC.”	No	N/A
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall.”	N/A
Migration	<p>“If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	<p><i>General Information:</i> “The Recovery G2 Filter is designed to act as a permanent filter. When clinically indicated, the Recovery G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the Recovery G2 Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p>
Fracture	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	<p><i>Directions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”</p>

Death	No	“All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”	N/A
Permanent Use	No	No	<p><i>General Information:</i> “The Recovery G2 Filter is designed to act as a permanent filter. When clinically indicated, the Recovery G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.”</p> <p><i>Indications for Use.</i> “The Recovery G2 Filter System Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p>

- This IFU identifies the device as the “Recovery G2” and appears to apply to Europe. The G2 device cleared by FDA on August 29, 2005 (for permanent use) was identified in the 510(k) application as “G2 Filter System.” (K050558) When the device was cleared for optional retrieval in January 2008 in the U.S., it was identified in the 510(k) application as “Recovery G2.” (K073090)
- This IFU does not include the “Clinical Experience” data/information (i.e. the Asch Study information) from Section I. Directions for Use as compared to the last available Recovery IFU in the U.S.

Recovery G2 IFU (EU) August 2006 (Jug, Rev. 0 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU) “The Recovery G2 Filter System – Jugular/Subclavian is designed for Jugular/Subclavian approaches only. Never use the Recovery G2 Filter System – Jugular/Subclavian for femoral approaches, as this may result in improper Recovery G2 Filter orientation within the IVC.”	No	N/A
Perforation	No	(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall.”	N/A
Migration	<p>(Note: Same as previous IFU) “If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p>(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	<p>(Note: Same as previous IFU) <i>General Information:</i> “The Recovery G2 Filter is designed to act as a permanent filter. When clinically indicated, the Recovery G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Recovery Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p>(Note: Same as previous IFU) <i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the Recovery G2 Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p>
Fracture	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) <i>Directions for Use - Clinical Experience:</i> “The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.”

Death	No	(Note: Same as previous IFU) “All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”	N/A
Permanent Use	<i>Filter Removal</i> “NOTE: It is possible that complications such as those described in the “Warnings, Precautions and Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”	No	(Note: Same as previous IFU) <i>General Information:</i> “The Recovery G2 Filter is designed to act as a permanent filter. When clinically indicated, the Recovery G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.” (Note: Same as previous IFU) <i>Indications for Use.</i> “The Recovery G2 Filter System Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”

C. G2 FILTER SYSTEM**G2 IFU August 2005 (Fem, Rev. 1 (Perm))**

Complication	Warnings	Potential Complications	Other Sections
Tilt	“The G2 Filter System is designed for femoral approaches only. Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2 Filter orientation within the IVC.”	No	N/A
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall”	N/A
Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	N/A
Fracture	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	N/A
Death	No	“All these above complications have been associated with serious adverse events such as medical intervention and/or death.”	N/A

Permanent Use	No	No	<p><i>General Information.</i> “The G2 Filter is designed to act as a permanent filter.”</p> <p><i>Precautions.</i> “The safety and effectiveness of the G2 filter as a retrievable or temporary filter have not been established.”</p>
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(BPV-17-01-00120840-845)

- In August 2005 Bard issued the initial G2 filter US IFU for the femoral application. (BPV-17-01-00120817-819)
- Revisions that are substantively identical in relevant language followed this IFU and are identified by Bard in Rule 26 disclosures (Robinson) as relevant G2 IFUs. The second revised IFU is dated August 2005. (BPV-17-01-00127336-340.) The third revised IFU is dated September 2005 (BPV-17-01-00127341-349.) The fourth revised IFU is dated April 2006. (BPV-17-01-00127350-358.) The fifth revised IFU is dated October 2006. (BPV-17-01-00127359-367)
- Revisions 2-6 appear to have related primarily to changes in artwork. (BPV-17-01-00127362)

G2 IFU September 2005 (Jug, Rev. 0 (Perm))

Complication	Warnings	Potential Complications	Other Sections
Tilt	“Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2 Filter orientation within the IVC.”	No	N/A
Perforation	No	(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall”	N/A
Migration	<p>“If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p>(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	N/A
Fracture	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	N/A
Death	No	“All these above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use use [sic] of vena cava filters in morbidly obese patients.”	N/A

Permanent Use	No	No	<p><i>Indications for Use.</i> “The G2 Filter System Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p> <p>(Note: Same as previous IFU) <i>General Information.</i> “The G2 Filter is designed to act as a permanent filter.”</p> <p><i>Precautions.</i> “The safety and effectiveness of the G2 filter as a retrievable or temporary filter have not been established.”</p>
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(BPV-17-01-00049053-058)

- In September 2005, Bard approved this initial G2 Filter IFU for the Jugular/Subclavian Approach. (BPV-17-01-00049053-058)
- A substantively identical jugular IFU dated December 2005 (Rev. 1) was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU. (BPV-17-01-00142863-870)

G2 IFU October 2006 (Jug, Rev. 2 (Perm))

Complication	Warnings	Potential Complications	Other Sections
Tilt	(Note: Same as previous IFU) “Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2 Filter orientation within the IVC.”	No	N/A
Perforation	No	(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall”	N/A
Migration	(Note: Same as previous IFU) “If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.” (Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	N/A
Fracture	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	N/A
Death	No	“All these above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”	N/A

Permanent Use	No	No	<p>(Note: Same as previous IFU)</p> <p><i>Indications for Use.</i> “The G2 Filter System Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p> <p><i>General Information.</i> “The G2 Filter is designed to act as a permanent filter.”</p> <p><i>Precautions.</i> “The safety and effectiveness of the G2 filter as a retrievable or temporary filter have not been established.”</p>
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- A Bates-numbered version of this IFU was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU. (BPV-17-01-00137425-432)
- There is a substantively identical G2 IFU for femoral delivery dated October 2006 (Rev. 5). (BPV-17-01-00137433-436.) It was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU.

G2 IFU January 2008 (Fem, Rev. 0 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	“Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2 Filter orientation within the IVC.”	No	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall”	<p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	(Note: Same as previous IFU) “Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”	<p><i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Fracture	“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in removal of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	(Note: Same as previous IFU) “Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”	<i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”
Death	No	“All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”	N/A
Permanent Use	No	No	<i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”

(BPV-17-01-00130944-947)

- This IFU is found within a G2 Express Special 510(k) application at Appx. 1, pages 59-62. The IFU is for the G2 filter system as the predicate device. (BPV-17-01-00130944-947)
- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU under at least three Bates numbers. (BPV-17-01-00127373-376 & BPV-17-01-00142938 & BPV-17-01-00144251)
- The femoral IFU dated March 2009 is substantively identical to the above in all relevant ways. (BPV-17-01-00137389-392)

G2 IFU January 2008 (Jug, Rev. 0 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	“Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2 Filter orientation within the IVC.”	No	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall”	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	<p>(Note: Same as previous IFU)</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	<p><i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in removal of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”</p>	<p>(Note: Same as previous IFU)</p> <p>“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A
Permanent Use	No	No	<p><i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p>

(BPV-17-01-00142946-953)

- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU. (BPV-17-01-00142946)

G2 IFU July 2009 (Fem, Rev. 1 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2 Filter orientation within the IVC.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p> <p>“Filter Tilt.”</p> <p>“Filter malposition.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena cava wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall. There was one symptomatic complication in the study. A patient reported low back pain after successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications include caudal migration (n=10, fracture (n=1, PE (n=2), filter tilt (n=15) penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall”	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena cava wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall. There was one symptomatic complication in the study. A patient reported low back pain after successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications include caudal migration (n=10, fracture (n=1, PE (n=2), filter tilt (n=15) penetration (n=17), caval</p>

Complication	Warnings	Potential Complications	Other Sections
			occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1)."
Migration	<p>"If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter."</p> <p>"Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens."</p>	<p>"Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens."</p>	<p>(Note: Same as previous IFU) <i>General Information</i> "The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed."</p> <p><i>Clinical Experience</i> "Asymptomatic complications include caudal migration (n=10, fracture (n=1, PE (n=2), filter tilt (n=15) penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1)."</p>
Fracture	<p>"Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques."</p>	<p>"Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of fragment utilizing endovascular and/or surgical technique."</p>	<p><i>Clinical Experience</i> "Asymptomatic complications include caudal migration (n=10, fracture (n=1, PE (n=2), filter tilt (n=15) penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1)."</p>
Death	No	<p>"All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients."</p>	N/A

Permanent Use	<i>G2 Filter Removal</i> “NOTE: It is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”	No	(Note: Same as previous IFU) <i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
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(BPV-17-01-00118398-401)

- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU under at least two Bates numbers. (BPV-17-01-00142942 & BPV-17-01-00144255)
- The femoral IFU dated October 2009 (Rev. 2) is substantively identical in all relevant ways. It was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU. (BPV-17-01-00137437-440)
- The jugular/subclavian IFU dated July 2009 (Rev. 1) is substantively identical in all relevant ways. It was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU under at least two Bates numbers. (BPV-17-01-00142954 & BPV-17-01-00144267)

G2 IFU October 2009 (Jug, Rev. 2 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>(Note: Same as previous IFU) “Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2 Filter orientation within the IVC.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Filter malposition”</p> <p>“Filter Tilt”</p>	<p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	<p>(Note: Same as previous IFU) “Perforation or other acute or chronic damage of the IVC wall”</p>	<p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p>(Note: Same as previous IFU) <i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2 Filter. If large thrombus is present at initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p>(Note: Same as previous IFU) <i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>(Note: Same as previous IFU) <i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A

Permanent Use	No	No	(Note: Same as previous IFU) <i>General Information</i> “The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter’s elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”
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(BPV-17-01-00137441)

- This IFU was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU. (BPV-17-01-00137441-448)
- There is a substantively identical G2 IFU for femoral delivery dated October 2009 (Rev. 2). (BPV-17-01-00137437-440). It was identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 IFU.

D. G2 EXPRESS FILTER**G2 Express IFU February 2008 (Fem, Rev. 0 (Optional))**

Complication	Warnings	Potential Complications	Other Sections
Tilt	“Never use the G2 Express Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2 Express Filter orientation within the IVC.”	No	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall.”	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.”</p> <p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	<p>“Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.”</p>	<p><i>General Information</i> “The G2 EXPRESS Filter is designed to act as a permanent filter. When clinically indicated, the G2 EXPRESS Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 EXPRESS Filter's anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”</p>	<p>“Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A
Permanent Use	<p>“NOTE: It is possible that complications such as those described in the “Warnings, Precautions and Potential Complications” section of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”</p>	No	<p><i>General Information</i> “The G2 EXPRESS Filter is designed to act as a permanent filter. When clinically indicated, the G2 EXPRESS Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure.”</p> <p><i>Indications for Use</i> “The G2X Filter – Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p>

(BPV-17-01-00137349-352)

- G2 Express Filter System and Delivery Kits were cleared by FDA July 30, 2008. The primary modification to the predicate Recovery G2 Filter System was the addition of a hook to the filter and minor dimensional changes to the filter systems to accommodate the new snare tip. (K080668) The modified delivery kits are often referred to as “G2X,” as is the filter and the entire system, after clearance of the kits on October 31, 2008. (K082305) (BPVE-01-00563065)

- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under at least three Bates numbers. (BPV-17-01-00137349-352 & BPV-17-01-00142919 & BPV-17-01-00144229)
- The jugular/subclavian IFU dated February 2008 (Rev. 0) is substantively identical to the above, with one exception: the *Directions for Use* section that states, “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2 Express Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.” This statement does not appear in the femoral *Directions for Use* section. The jugular/subclavian IFU has been identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under at least three Bates numbers. (BPV-17-01-00137353-364 & BPV-17-01-00142920 & BPV-17-01-00144233)
- The “G2X” IFU for femoral delivery dated March 2009 (Rev. 0) is substantively identical in all relevant ways to this IFU with one exception. It includes the Warning in the *Directions for Use* section quoted above from the February 2008 (Rev. 0) jugular/subclavian IFU. It was identified in Bard’s Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under at least two Bates numbers. (BPV-17-01-00137401-412 & BPV-17-01-00142395-406)
- The “G2X” IFU for jugular delivery dated March 2009 (Rev. 0) is substantively identical in all relevant ways to the jugular/subclavian IFU dated February 2008 (Rev. 0) quoted in the bullet point above. It includes the same Warning under *Directions for Use* that is not included in the femoral counterpart. It was identified in Bard’s Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under at least two Bates numbers. (BPV-17-01-00137413-424 & BPV-17-01-00142407-418)

G2 EXPRESS IFU May 2009 (Jug, Rev. 0 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2X Filter orientation within the IVC.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Filter malposition.”</p> <p>“Filter Tilt.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	<p>“Perforation or other acute or chronic damage of the IVC wall.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introduce sheath.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p><i>General Information</i> “The G2X is designed to act as a permanent filter. When clinically indicated, the G2X Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2X Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p> <p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2X Filter. If large thrombus is present at initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p>
Fracture	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A

Permanent Use	<p>“NOTE: It is possible that complications such as those described in the “Warnings,” “Precautions” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”</p>	<p><i>General Information</i> “The G2X is designed to act as a permanent filter. When clinically indicated, the G2X Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2X Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Indications for Use</i> “The G2X Filter – Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations”</p>
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(BPVE-01-00605621-720)

- The jugular/subclavian IFU dated June 2009 (Rev. 4) is substantively identical in all relevant ways. (BPV-DEP-00010754-773) It has been identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2X IFU under at least two Bates numbers. (BPV-17-01-00142972 & BPV-17-01-00144177)
- The G2X IFU for femoral delivery dated June 2009 (Rev. 4) is substantively identical in all relevant ways and has been identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2X IFU. (BPV-17-01-00142962 & BPV-17-01-00144167)

G2 EXPRESS IFU October 2009 (Fem, Rev. 5 (Optional))

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Never use the G2X Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2X Filter orientation within the IVC.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Filter malposition.”</p> <p>“Filter Tilt.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	<p>“Perforation or other acute or chronic damage of the IVC wall.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p><i>General Information</i> “The G2X is designed to act as a permanent filter. When clinically indicated, the G2X Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2X Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2X Filter. If large thrombus is present at initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A

Permanent Use	<p>“NOTE: It is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential Complications” sections of these Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”</p>	No	<p><i>General Information</i> “The G2X is designed to act as a permanent filter. When clinically indicated, the G2X Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2X Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Indications for Use</i> “The G2X Filter – Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p>
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(BPV-17-01-00137365)

- This IFU is identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under this Bates and at least one other. (BPV-17-01-00137365 & BPV-17-01-00142371-382)
- The jugular/subclavian IFU dated October 2009 (Rev. 5) is substantively identical in all relevant ways. It also has been identified by Bard in Rule 26 disclosures (Robinson) as a relevant G2 Express IFU under at least two Bates numbers (BPV-17-01-00137377-388 & BPV-17-01-00142383-394)

E. ECLIPSE**Eclipse IFU December 2009 (Fem, Rev. 0a (Optional))**

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“The Eclipse Filter – Femoral is designed for femoral approaches only. Never use the Eclipse Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Eclipse Filter orientation within the IVC.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Filter malposition”</p> <p>“Filter tilt”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of the filter apex into caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	<p>“Perforation or other acute or chronic damage of the IVC wall.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of the filter apex into caval wall.”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through and alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p><i>General Information</i> “The Eclipse Filter is designed to act as a permanent filter. When clinically indicated, the Eclipse Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Eclipse Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm do not deploy the Eclipse Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A

Permanent Use	<p>“NOTE: It is possible that complications such as those described in the “Warnings”, “Precautions,” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”</p>	No	<p><i>General Information</i> “The Eclipse Filter is designed to act as a permanent filter. When clinically indicated, the Eclipse Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Eclipse Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Indications for Use</i> “The Eclipse Filter – Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p>
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(BPV-17-01-00142879)

- The jugular/subclavian IFU dated December 2009 (Rev. 0a) is substantively identical in all relevant ways. (BPV-17-01-00142888.) Both IFUs have been identified by Bard in Rule 26 disclosures (Robinson) as relevant Eclipse IFUs.
- This IFU is also found at Bates BPV-17-01-00144136. The jugular/subclavian IFU Dated December 2009 (Rev. 0a) is also found at Bates BPV-17-01-00144145.

F. MERIDIAN**Meridian IFU October 2010 (Fem, Rev. 0)**

Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“The Meridian Filter – Femoral is designed for femoral approaches only. Never use the Meridian Filter and delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Meridian Filter orientation within the IVC.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters.”</p> <p>“Filter malposition”</p> <p>“Filter Tilt”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of the filter apex into caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Perforation	No	<p>“Perforation or other acute or chronic damage of the IVC wall.”</p>	<p><i>Clinical Experience</i> “Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of the filter apex into caval wall.”</p> <p><i>Clinical Experience</i> “On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>

Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p><i>General Information</i> “The Meridian Filter is designed to act as a permanent filter. When clinical indicated, the Meridian Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Meridian Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Directions for Use</i> “WARNING: If the vena cava diameter is greater than 28mm, do not deploy the Meridian Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”</p> <p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Fracture	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p>	<p><i>Clinical Experience</i> “Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).”</p>
Death	No	<p>“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”</p>	N/A

Permanent Use	<p>“NOTE: It is possible that complications such as those described in the “Warnings”, “Precautions,” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”</p>	No	<p><i>General Information</i> “The Meridian Filter is designed to act as a permanent filter. When clinical indicated, the Meridian Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Meridian Filter’s anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed.”</p> <p><i>Indications for Use</i> “The Meridian Filter – Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”</p>
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(BPV-17-01-00147623-34)

- The jugular/subclavian IFU dated October 2010 (Rev. 0) is substantively identical in all relevant ways. (BPV-17-01-00147683-94.)
- The jugular/subclavian IFU dated December 2010 (Rev. 1) is substantively identical in all relevant ways. (BPV-17-01-00147695-706)
- The femoral IFU dated January 2011 (Rev. 1) is substantively identical in all relevant ways. (BPV-17-01-00147635-46)
- The femoral IFU dated February 2011 (Rev. 2) is substantively identical in all relevant ways. (BPV-17-01-00147647-58)
- The jugular/subclavian IFU dated June 2011 (Rev. 2) is substantively identical in all relevant ways. (BPV-17-01-00147707-18)
- The femoral IFU dated June 2011 (Rev. 3) is substantively identical in all relevant ways. (BPV-17-01-00147659-70)
- The jugular/subclavian IFU dated August 2011 (Rev. 3) is substantively identical in all relevant ways. (BPV-17-01-00147719-30)
- The femoral IFU dated June 2011 (Rev. 3) is substantively identical in all relevant ways. (BPV-17-01-00147671-82)

G. DENALI**DENALI IFU September 2011 (Jug, Rev. 0 (Optional))**

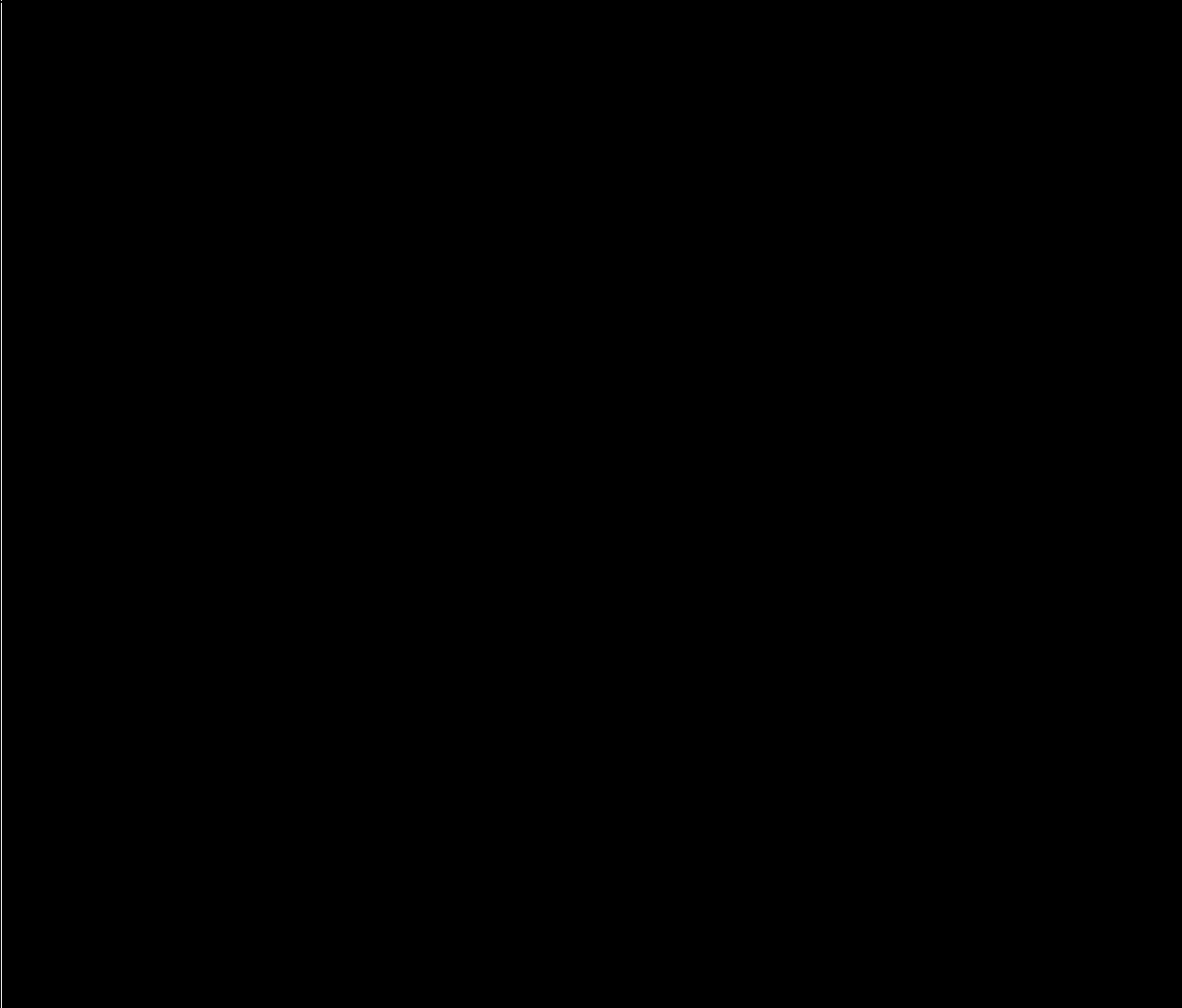
Complication	Warnings	Potential Complications	Other Sections
Tilt	<p>“The Denali Filter Jugular/Subclavian System is designed for Jugular/Subclavian approaches only. Never use the Denali Filter Jugular/Subclavian System for femoral approaches, as this will result in improper filter orientation within the IVC.”</p> <p>“Movement, migration or tilt are known complications of vena cava filters.”</p>	<p>“Movement, migration or tilt are known complications of vena cava filters.”</p> <p>“Filter malposition.”</p> <p>“Filter tilt.”</p>	N/A
Perforation	No	“Perforation or other acute or chronic damage of the IVC wall.”	N/A
Migration	<p>“If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.”</p> <p>“Movement, migration or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration. Migration may be caused by placement of the filter in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<p>“Movement, migration or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.”</p>	<i>Directions for Use – Implantation</i> “If large thrombus is present at the initial deliver site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.”
Fracture	“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”	<p>“Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.”</p> <p>“Detachment of components”</p>	N/A

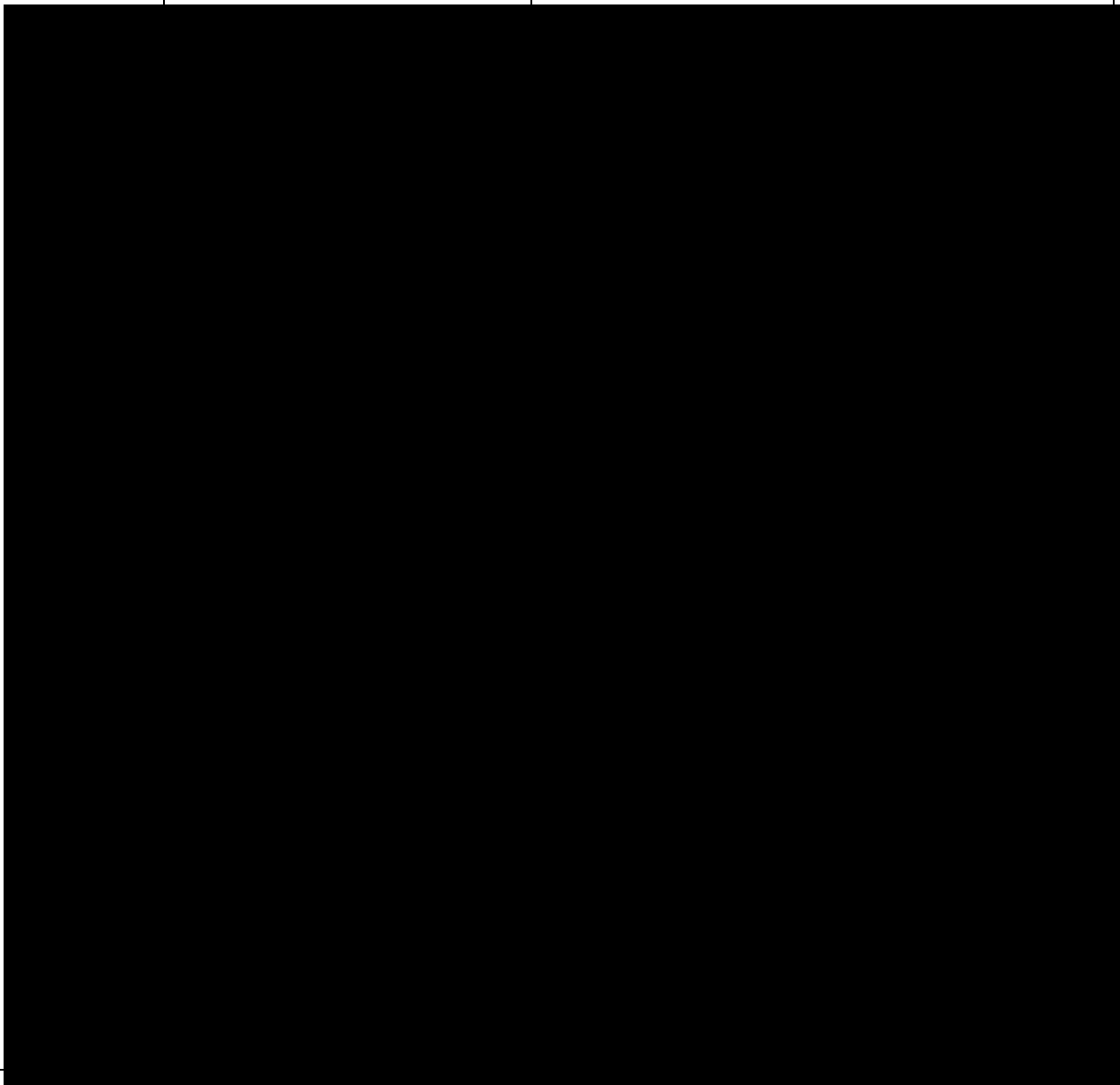
Death	No	“All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.”	N/A
Permanent Use	“Note: It is possible that complications such as those described in the “Warnings”, “Precautions”, or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.”		<i>Indications for Use</i> “The Denali Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations.”

(BPVEFILTER-01-00542477-580)

Schedule 9 – Summary of HHEs

Schedule 9 – Summary of HHEs

HHE Date	Starting Bates	Author	Subject	Summary And Conclusion	Important Quotes
3/10/2004	BPVE- 01- 00510989	John Lehmann, M.D.			

				Cava Filter.”	
4/27/2004	BPVE FILTER- 01- 00043728	John Lehmann, M.D.			

6/30/2004	BPVE FILTER- 01- 0014836	David Ciavarella, M.D.	Migration of the Recovery Filter	

7/9/2004	BPV- DEP- 0004730	David Ciavarella, M.D.	

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11/17/2004	BPV-17-01-00103875	David Ciavarella, M.D.	Updated HHE re: Limb Fractures of the Recovery Filter	

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12/17/2004	BPVE-01-01019821	David Ciavarella, M.D.	

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2/15/2006	BPVE FILTER- 01- 00008355	David Ciavarella, M.D.	

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